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Title 3—

The President

Proclamation 9908 of July 14, 2019

Made in America Day and Made in America Week, 2019

By the President of the United States of America

A Proclamation

On Made in America Day and during Made in America Week, we honor the extraordinary efforts of American entrepreneurs, workers, and farmers in revitalizing our Nation's economy. Products made in America are the world standard for quality and showcase the craftsmanship of the most innovative, diverse, highly skilled, and dedicated workforce in the world.

When we buy American-made products, we support the American workers who build them and we invigorate the American economy, driving job growth, spurring innovation, and bolstering the middle class. We have already witnessed the creation of more than 6 million new jobs since my election, and wages are rising at the highest pace in a decade. Through historic tax and regulatory reform, workforce initiatives, trade enforcement, and the negotiation of new trade deals, my Administration is fulfilling our promise to make ''buy American and hire American'' the new standard. My Administration is striving to ensure that items purchased by the Government are made in America, with American materials, and by American hands.

Thanks to the enactment of the Tax Cuts and Jobs Act and the elimination of burdensome and unnecessary regulations, American workers and entrepreneurs have renewed confidence. American companies are becoming more competitive with their foreign counterparts and have more money to invest in their employees through bonuses, higher wages, and increased contributions to retirement plans.

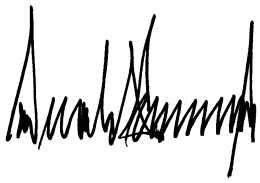
My Administration is also pursuing fair trade by working to level the playing field so that American companies can compete in an increasingly global market. To fight against unfair trade practices, we are vigorously enforcing our Nation's existing trade laws. We significantly updated one of our most consequential trade deals, the United States-Korea Free Trade Agreement (KORUS) to make it more beneficial to American workers. I also delivered on my promise to renegotiate the outdated and unbalanced North American Free Trade Agreement (NAFTA) with the signing of the United States-Mexico-Canada Agreement (USMCA). Once approved by the Congress, the USMCA will help reverse longstanding trade imbalances by granting American businesses across all sectors of our economy greater freedom to sell their goods and services throughout North America.

Last year, I signed an Executive Order establishing the President's National Council for the American Worker and the American Workforce Policy Advisory Board to focus on retraining our workforce and equipping students and workers with the skills they need to be successful across high-demand industries. We are asking companies to commit to expanding programs that educate, train, and re-skill American workers of all ages by signing our Pledge to America's Workers.

It is imperative that we keep investing in the industrious American workers, job creators, and inventors who always succeed at leading in innovation and ingenuity, and never fail to inspire the rest of the world. My Administration will always back our American workers and manufacturers as they continue their hard work to keep the American economy strong and propel our Nation toward a more prosperous future.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 15, 2019, as Made in America Day and this week, July 14 through July 20, 2019, as Made in America Week. I call upon all Americans to pay special tribute to the builders, the ranchers, the crafters, the entrepreneurs, and all those who work with their hands every day to make America great.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of July, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–15448
Filed 7–17–19; 8:45 am]
Billing code 3295–F9–P

Presidential Documents

Executive Order 13881 of July 15, 2019

Maximizing Use of American-Made Goods, Products, and Materials

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to promote the principles underlying the Buy American Act of 1933 (41 U.S.C. 8301–8305), it is hereby ordered as follows:

Section 1. *Policy*. (a) As expressed in Executive Order 13788 of April 18, 2017 (Buy American and Hire American), and in Executive Order 13858 of January 31, 2019 (Strengthening Buy-American Preferences for Infrastructure Projects), it is the policy of the United States to buy American and to maximize, consistent with law, the use of goods, products, and materials produced in the United States. To those ends, my Administration shall enforce the Buy American Act to the greatest extent permitted by law.

(b) In Executive Order 10582 of December 17, 1954 (Prescribing Uniform Procedures for Certain Determinations Under the Buy-American Act), President Eisenhower established that materials shall be, for purposes of the Buy American Act, considered of foreign origin if the cost of the foreign products used in such materials constitutes 50 percent or more of the cost of all the products used in such materials. He also established that, in determining whether the bid or offered price of materials of domestic origin is unreasonable or inconsistent with the public interest, the executive agencies shall either (1) add 6 percent to the total bid or offered price of materials of foreign origin, or (2) add 10 percent to the total bid or offered price of materials of foreign origin less certain specified costs as follows. Where the foreign bid or offer is less than $25,000, applicable duty is excluded from the calculation. Where the foreign bid or offer is more than $25,000, both applicable duty, and all costs incurred after arrival in the United States, are excluded from the calculation.

(c) The policies described in section 1(b) of this order were adopted by the Federal Acquisition Regulatory Council (FAR Council) in the Federal Acquisition Regulation (FAR), title 48, Code of Federal Regulations. The FAR should be reviewed and revised, as appropriate, to most effectively carry out the goals of the Buy American Act and my Administration's policy of enforcing the Buy American Act to its maximum lawful extent. I therefore direct the members of the FAR Council to consider measures that may better effectuate this policy.

Sec. 2. *Proposed Rules*. (a) Within 180 days of the date of this order, the FAR Council shall consider proposing for notice and public comment:

(i) an amendment to the applicable provisions in the FAR that would provide that materials shall be considered to be of foreign origin if:

(A) for iron and steel end products, the cost of foreign iron and steel used in such iron and steel end products constitutes 5 percent or more of the cost of all the products used in such iron and steel end products; or

(B) for all other end products, the cost of the foreign products used in such end products constitutes 45 percent or more of the cost of all the products used in such end products; and

(ii) an amendment to the applicable provisions in the FAR that would provide that the executive agency concerned shall in each instance conduct the reasonableness and public interest determination referred to in sections 8302 and 8303 of title 41, United States Code, on the basis of the following-described differential formula, subject to the terms thereof: the sum determined by computing 20 percent (for other than small businesses), or 30 percent (for small businesses), of the offer or offered price of materials of foreign origin.

(b) The FAR Council shall consider and evaluate public comments on any regulations proposed pursuant to section 2(a) of this order and shall promptly issue a final rule, if appropriate and consistent with applicable law and the national security interests of the United States. The head of each executive agency shall issue such regulations as may be necessary to ensure that agency procurement practices conform to the provisions of any final rule issued pursuant to this order.

Sec. 3. *Effect on Executive Order 10582*. Executive Order 10582 is superseded to the extent that it is inconsistent with this order. Upon the issuance of a final rule pursuant to section 2 of this order, subsections 2(a) and 2(c) of Executive Order 10582 are revoked.

Sec. 4. *Additional Actions*. Within 180 days of the date of this order, the Secretary of Commerce and the Director of the Office of Management and Budget shall, in consultation with the FAR Council, the Chairman of the Council of Economic Advisers, the Assistant to the President for Economic Policy, and the Assistant to the President for Trade and Manufacturing Policy, submit to the President a report on any other changes to the FAR that the FAR Council should consider in order to better enforce the Buy American Act and to otherwise act consistent with the policy described in section 1 of this order, including whether and when to further decrease, including incrementally, the threshold percentage in subsection 2(a)(i)(B) of this order from the proposed 45 percent to 25 percent. The report shall include recommendations based on the feasibility and desirability of any decreases, including the timing of such decreases.

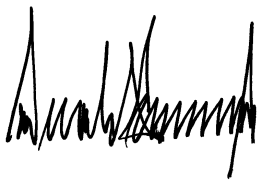
Sec. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof, including, for example, the authority to utilize non-availability and public interest exceptions as delineated in section 8303 of title 41, United States Code, and 48 CFR 25.103; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
July 15, 2019.

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AH17

Small Business Size Standards: Adjustment of Monetary-Based Size Standards for Inflation

AGENCY: U.S. Small Business Administration.

ACTION: Interim final rule with request for comments.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) is adjusting the monetary-based industry size standards (*i.e.,* receipts- and assets-based) for inflation that has occurred since the last adjustment in 2014. These size standards will be reviewed again as part of the ongoing second 5-year review of size standards, as mandated by the Small Business Jobs Act of 2010 (Jobs Act). Also adjusted for inflation are receipts-based size standards that apply to sales or leases of Government property and stockpile purchases.

DATES: *Effective Date:* This rule is effective August 19, 2019.

Comment Date: Comments must be received on or before September 16, 2019.

ADDRESSES: You may submit comments, identified by RIN 3245–AH17, by any of the following methods: (1) Federal eRulemaking Portal: *https://www.regulations.gov*, following the specific instructions for submitting comments; or (2) Mail/Hand Delivery/Courier: U.S. Small Business Administration, Khem R. Sharma, Ph.D., Chief, Office of Size Standards, 409 Third Street SW, Mail Code 6530, Washington, DC 20416.

SBA will post all comments to this interim final rule on *https://www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *https://www.regulations.gov,* you must submit such information to the U.S. Small Business Administration, Khem R. Sharma, Ph.D., Chief, Office of Size Standards, 409 Third Street SW, Mail Code 6530, Washington, DC 20416, or send an email to *sizestandards@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review your information and determine whether it will make the information public.

FOR FURTHER INFORMATION CONTACT: Jorge Laboy-Bruno, Ph.D., Office of Size Standards, (202) 205–6618 or *sizestandards@sba.gov.*

SUPPLEMENTARY INFORMATION: As explained in the SBA's ''Size Standards Methodology'' white paper available at *https://www.sba.gov/size* and at *https://www.regulations.gov* (Docket ID: SBA–2018–0004), SBA reviews small business size standards and makes necessary adjustments to them for two reasons: (i) Changes in industry structure and Federal market conditions and (ii) inflation. Prior to the 2014 inflation adjustment, SBA reviewed all monetary-based industry size standards with respect to industry structure and Federal market conditions as part of the first 5-year review of size standards required by section 1344 of the Small Business Jobs Act of 2010 (Jobs Act) (Pub. L. 111–240, 124 Stat. 2504 (September 27, 2010)). In this rule, SBA is adjusting its monetary-based industry size standards for inflation that has occurred since the last inflation adjustment, which was published in June 2014 (79 FR 33647 (June 12, 2014)). These include receipts-based size standards for 518 industries and 9 subindustries (*i.e.,* ''exceptions'' in the SBA Table of Size Standards), as well as assets-based size standards for 5 industries. As part of the ongoing second 5-year review of size standards required by the Jobs Act, SBA will review these size standards again in the near future to determine whether further adjustments are needed based on industry and Federal market conditions. Additionally, SBA is adjusting 2 program-specific receipts-based size standards, namely, (1) sales or leases of Government property and (2) stockpile purchases. However, as explained elsewhere in this rule, SBA is not adjusting either (1) the tangible net worth and net income-based alternative size standard established under the Jobs Act for its 7(a) and 504 Loan Programs; or (2) the tangible net worth and net income-based alternative size standard established for the Small Business Investment Company (SBIC) Program.

SBA is required to assess the impact of inflation on its monetary-based size standards at least once every 5 years (*see* SBA Interim Final Rule: Small Business Size Standards: Inflation Adjustment to Monetary Based Size Standards (67 FR 3041 (January 23, 2002)) and 13 CFR 121.102(c)). Although the provision does not mandate that SBA actually adjust size standards for inflation every 5 years, it does provide assurances to the public that the Agency is monitoring inflation to determine whether or not to adjust size standards within a reasonable period of time since its last inflation adjustment.

Previous inflation adjustments to size standards were in SBA's Interim Final Rule: Small Business Size Standards: Inflation Adjustment to Monetary Based Size Standards ((79 FR 33647 (June 12, 2014)) (SBA Final Rule at 81 FR 3949 (January 25, 2016) finalized the 2014 IFR without change); in SBA Final Rule: Small Business Size Standards: Inflation Adjustment to Size Standards, Business Loan Program, and Disaster Assistance Loan Program (73 FR 41237 (July 18, 2008)); SBA Interim Final Rule: Small Business Size Standards, Inflation Adjustment to Size Standards; Business Loan Program; Disaster Assistance Loan Program (70 FR 72577 (December 6, 2005)); SBA Final Rule: Small Business Size Standards: Inflation Adjustment to Size Standards (67 FR 65285 (October 24, 2002)); SBA Interim Final Rule: Small Business Size Standards; Inflation Adjustment to Size Standards (67 FR 3041 (January 23, 2002)); SBA Final Rule: Small Business Size Standards; Inflation Adjustment to Size Standards (59 FR 16513 (April 7, 1994)); SBA Final Rule: Small Business Size Standards; Revision (49 FR 5024 (February 9, 1984)); and SBA Final Rule: Small Business Size Standards Regulation (40 FR 32824 (August 5, 1975)).

A number of businesses may have lost small business eligibility for Federal assistance under SBA's monetary-based industry size standards simply because of inflation-led revenue growth that has occurred since the 2014 adjustment. This rule aims to reinstate those firms'

small business eligibility for Federal assistance.

As mentioned above, the adjustment for inflation in this rule applies to all monetary-based industry size standards, including the $750,000 receipts-based size standard for agricultural industries, which was previously set by statute. However, section 1831 of the National Defense Authorization Act for Fiscal Year 2017 (NDAA 2017) (Pub. L. 114–328, 130 Stat. 2000, December 23, 2016) directed SBA to establish size standards for all agricultural enterprises in the same manner as for other industries and to include them in the 5-year rolling review procedures established under section 1344(a) of the Jobs Act.

The inflation adjustments in this rule are separate from revisions to size standards made during the 5-year rolling reviews of size standards, as mandated by the Jobs Act. SBA's 5-year size standards rolling reviews primarily focus on industry structure (*i.e.,* average firm size, startup costs and entry barriers, industry concentration, and distribution of firms by business size) and Federal contracting trends (*i.e.,* small business share of Federal contract dollars relative to small business share of total industry's receipts) for industries with significant contracting activities.

Rather than reviewing all size standards at one time, for the 5-year rolling reviews, SBA reviews size standards on a Sector-by-Sector basis over a period. The objective of the rolling review is to review all size standards and make necessary adjustments to reflect current industry structure and Federal market conditions. By including inflation as an additional factor in the analysis, it would mean applying different inflation rates to different sectors at different times. For example, the applicable inflation would be lower for sectors reviewed earlier in the cycle and higher for those reviewed later in the cycle, resulting in inconsistent size standards across sectors and industries. To avoid this, SBA has decided to evaluate all monetary industry-based size standards for inflation separate from the 5-year rolling review.

Updating size standards based on inflation—in addition to updating size standards based on the latest industry and Federal contracting data under the 5-year rolling review—not only satisfies the Jobs Act's mandate that SBA review all size standards, but also is consistent with Executive Order 13563 on improving regulation and regulatory review. This also fulfills the SBA's regulatory requirement to review size standards for inflation every 5 years.

SBA's Inflation Adjustment Methodology

For this interim final rule, SBA has used the inflation adjustment methodology it described in its ''Size Standards Methodology'' white paper, which is available at *https://www.sba.gov/size.* SBA applied the same methodology in its previous inflation adjustments, including the latest adjustment in 2014. This methodology can be described in terms of the following steps:

1. Selecting an inflation measure.
2. Selecting the base and end periods.
3. Calculating the inflation rate.
4. Adjusting the monetary based size standards.

1. Selecting an Inflation Measure

SBA establishes small business size standards to determine the eligibility of businesses for a wide variety of SBA's and other Federal programs. Many businesses participating in those programs are engaged in multiple industries and are producing a wide range of goods and services. Therefore, it is important that the Agency use a broad measure of inflation to adjust its size standards. SBA's preferred measure of inflation has consistently been the chain-type price index for the U.S. Gross Domestic Product (GDP price index), published by the U.S. Department of Commerce, Bureau of Economic Analysis (BEA) on a quarterly basis as part of its National Income and Product Accounts (NIPA) and available at *https://www.bea.gov/iTable.*

In its 2014 interim final rule (79 FR 33647 (June 12, 2014)), besides the GDP price index, SBA reviewed several alternative inflation measures published by the Federal Government (including the consumer price index, the personal consumption expenditures price index, the producer price index, and the employment cost index) for their appropriateness to use for adjusting SBA's size standards. Among all these indexes, SBA determined that the GDP price index is the most comprehensive measure of movements in the general price level in the economy and thus the most appropriate measure of inflation for adjusting SBA's size standards. Thus, as in the previous inflation adjustments, SBA has decided to use the GDP price index to adjust monetary-based size standards for the current inflation adjustment.

2. Selecting the Base and End Periods

For this inflation adjustment (excluding the $750,000 agricultural size standard adjustment), SBA selected the first quarter of 2014 as the base period because it was the end period for the 2014 adjustment. SBA selected the fourth quarter of 2018 as the end period because it was the latest quarter for which GDP price indexes were available when that rule was developed.

The current $750,000 size standard for agricultural industries was established by Congress in December of 2000 (Pub. L. 106–554, 114 Stat. 2763, Dec. 21, 2000) and was not included in previous inflation adjustments. However, section 1831 of the NDAA 2017 directed SBA to review and adjust size standards for all agricultural enterprises in the same manner as for other industries. Thus, in this rule, SBA is also adjusting the $750,000 size standard for agricultural industries by using the first quarter of 2001 as the base period and the fourth quarter of 2018 as the end period.

3. Calculating the Rate of Inflation

The GDP price index for the base period (excluding the $750,000 agricultural size standard) was 102.551 and the GDP price index for the end period was 111.134. Accordingly, inflation increased 8.37 percent from the first quarter of 2014 to the fourth quarter of 2018 $(((111.134 \div 102.551) - 1) \times 100$ percent = 8.37 percent).

The GDP price index for the agricultural base period was 79.232 and the GDP price index for the agricultural end period was 111.134. Accordingly, inflation increased 40.26 percent from the first quarter of 2001 to the fourth quarter of 2018 $(((111.134 \div 79.232) - 1) \times 100$ percent = 40.26 percent).

4. Making Adjustments to Size Standards

Adjustment to receipts-based industry size standards: All receipts-based size standards (excluding the $750,000 agricultural size standard) were adjusted by multiplying their current levels by 1.0837 and rounding the results to the nearest $500,000.

Adjustment to the agricultural size standard: SBA multiplied the current size standard of $750,000 for 46 agricultural industries by 1.4026 to obtain a non-rounded size standard of $1.05 million. Rounding to the nearest $500,000 results in an adjusted size standard of $1.0 million for all 46 agricultural industries.

Adjustment to the assets-based size standard: Currently, 5 industries in North American Industry Classification System (NAICS) Sector 52, Finance and Insurance, have the size standard of $550 million in average assets. Following the inflation adjustment methodology described above, the assets-based size standard was adjusted

by multiplying the current value of $550 million by 1.0837. The result was $596 million, which SBA rounded to $600 million.

Table 1, ''Inflation Adjustment to Monetary-based Size Standards,'' summarizes the results of the inflation adjustment for 16 different receipts-based size standards levels, ranging from $0.75 million to $38.5 million, as well as one assets-based size standard of $550 million. The first column of Table 1 shows the current monetary-based industry size standards; the second column shows their inflation-adjusted values before rounding; the third column shows their inflation-adjusted values after rounding; and the fourth column shows the count of industries and subindustries (or ''exceptions'') that are associated with each of the receipts- and assets-based size standards levels. The results lead to adjustment to 532 size standards, including 523 industries and 9 subindustries or ''exceptions.''

TABLE 1—INFLATION ADJUSTMENT TO MONETARY-BASED SIZE STANDARDS

Current monetary-based size standards ($ million) (1)	Size standards adjusted for inflation, before rounding ($ million) (2)	Size standards adjusted for inflation, after rounding ($ million) (3)	Number of industries (incl. exceptions) (4)
$ 0.75	$1.05	$1.0	46
5.5	6.0	6.0	4
7.5	8.1	8.0	126
11.0	11.9	12.0	39
15.0	16.3	16.5	95
18.0	19.5	19.5	1
19.0	20.6	20.5	2
20.5	22.2	22.0	39
25.0	27.1	27.0	1
27.5	29.8	30.0	55
29.5	32.0	32.0	3
32.0	34.7	34.5	2
32.5	35.2	35.0	39
36.5	39.6	39.5	11
37.5	40.6	40.5	1
38.5	41.7	41.5	63
550	596	600	5
Total Industries (including subindustries or ''exceptions'')			532

Adjustment to program-based size standards: Most SBA and other Federal programs apply SBA's industry-based size standards. SBA has also established a few size standards on a program basis rather than on an industry basis. Some of these size standards are also adjusted for inflation in the same manner as the receipts-based and assets-based industry size standards. Table 2, ''Inflation Adjustment to Program-based Receipts Size Standards,'' shows the program-based size standards and their corresponding inflation-adjusted values. The size standard for ''smaller enterprises'' under the Small Business Investment Company (SBIC) program is set by regulation (*see* 13 CFR 107.710(a)) and, therefore, not adjusted. SBA is also electing not to adjust the SBIC program's tangible net worth and net income-based alternate size standard in 13 CFR 121.301(c). SBA adjusted the tangible net worth and net income alternate size standard for the SBIC program for inflation in 2014 (79 FR 33647 (June 12, 2014)). SBA has determined that the current SBIC alternative size standard levels are enough to accomplish its program objectives and that no further increase is necessary at this time.

TABLE 2—INFLATION ADJUSTMENT TO PROGRAM-BASED RECEIPTS SIZE STANDARDS

Program	CFR citation	Size standard in millions of dollars	
		Current size standard	Inflation-adjusted size standard
Sales or leases of Government property	13 CFR 121.502(a)(2)	$7.5	$8.0
Stockpile purchases	13 CFR 121.512	62.5	67.5

Special Considerations

Size Standard for Leasing of Building Space to the Federal Government by Owners—Footnote 9: The size standard found in Footnote 9 to 13 CFR 121.201 (Leasing of Building Space to the Federal Government by Owners) was also adjusted for inflation. The current size standard of $38.5 million was multiplied by 1.0837 to obtain an adjusted size standard of $41.5 million after rounding. As explained more fully in the prior Inflation Adjustment (79 FR 33647), this size standard exception applies to all 4 industries in NAICS Group 5311, Lessors of Real Estate.

Alternative Size Standard for 7(a) and 504 Loan Programs: Effective September 27, 2010, Congress established through the Jobs Act a new temporary alternative size standard of tangible net worth of not more than $15 million and net income of not more than $5 million for SBA's 7(a) and 504 Loan Programs. On September 29, 2010, SBA issued Information Notice 5000–1175 (available at *https://www.sba.gov/sites/*

default/files/files/bank_5000-1175_0.pdf) advising lenders and the public that, effective September 27, 2010, the new statutory alternative size standard will apply for its 7(a) and 504 Loan Programs, thereby replacing the existing alternative size standard of $8.5 million in tangible net worth and $3 million in net income, then set forth in 13 CFR 121.301(b)(2). The Jobs Act also provided that the new temporary alternative size standard would remain in effect for the 7(a) and 504 Loan Programs until the SBA's Administrator establishes a different size standard through rulemaking. For this reason, in this rule, SBA is not adjusting the new alternative size standard for its 7(a) and 504 Loan programs for inflation. SBA will issue a different rule to establish a permanent alternative size standard for those programs.

Justification for Updating Size Standards for Inflation as an Interim Final Rule

In general, to revise or update size standards, SBA publishes a proposed rule for public comment before issuing a final rule, in accordance with the Administrative Procedure Act (APA), 5 U.S.C. 553, and SBA regulations, 13 CFR 101.108. The APA provides an exception to this standard rulemaking process, however, in situations where an agency finds good cause to adopt a rule without prior public participation. (*See* 5 U.S.C. 553(b)(3)(B)). The good cause requirement is satisfied when prior public participation is impracticable, unnecessary, or contrary to the public interest. Under those conditions, an agency may publish an interim final rule without first soliciting public comment. In applying the good cause exception to the standard rulemaking process, Congress recognized that special circumstances might arise justifying issuance of a rule without prior public participation.

As stated above, the last time SBA made inflation adjustments to size standards was 2014. A number of businesses may have lost small business eligibility for Federal assistance under SBA's monetary-based size standards simply as a result of the inflation that has occurred since that time. This rule is necessary to make those businesses eligible for Federal assistance. Any delay in the adoption of inflation-adjusted size standards could cause significant harm to those businesses and others that are about to exceed current size standards simply due to inflation-driven revenue growth. Immediate implementation of this rule would enable more businesses to qualify under SBA's monetary-based size standards, which would enable them to apply for Federal small business assistance and thereby create jobs.

The standard notice and comment rulemaking could delay the implementation of this rule by at least 8 to 12 months. Such a delay would be contrary to the public interest as it would delay the eligibility of those businesses for Federal small business assistance, perhaps forcing some of them to cease operations before a final rule could be promulgated under the standard rulemaking process. Furthermore, the inflation adjustment will become outdated by the time the final rule is published under notice and comment rulemaking.

For the above reasons, SBA finds that good cause exists to publish this rule as an interim final rule. SBA's rationale for preparing this action as an interim final rule and giving it immediate effect is consistent with the Agency's statutory obligation to protect the interests of small businesses, thereby enabling them to maintain competitiveness and strengthen the overall economy. Small Business Act, 15 U.S.C. 631(a). SBA had also implemented inflation adjustments to size standards through an interim final rule in 2002, 2005, and 2014 without any controversies.

By publishing this rule as an interim final rule, SBA is not excluding public participation in the rulemaking process. SBA is soliciting comments from interested parties on this interim final rule on a number of issues, including SBA's methodology for inflation adjustment and alternative measures of inflation. SBA will evaluate all comments and revise, if necessary, this rule, and publish a final rule at a later date.

Request for Comments

SBA seeks comments on this rule, specifically on the following issues:

1. SBA welcomes comments from interested parties on SBA's size standards methodology for inflation adjustment to its size standards. Specifically, SBA seeks comment on whether the GDP price index is an appropriate measure of inflation for adjusting size standards. The Agency invites suggestions, along with supporting data and analysis, if a different measure of inflation would be more appropriate.

2. SBA also invites comments on whether it should adjust employee-based industry size standards for labor productivity growth and technological advancements, similar to adjusting monetary-based industry size standards for inflation.

3. SBA also invites comments on any other aspects of this rulemaking, including the changes to program-based and assets-based size standards.

Compliance With Executive Orders 12866, 13563, 12988, 13132, and 13771, the Paperwork Reduction Act (44 U.S.C., Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this interim final rule is not a ''significant regulatory action'' for purposes of Executive Order (E.O.) 12866. However, in order to help explain the need for this rule and its potential benefits and costs, SBA is providing below a Cost/Benefit Analysis of the rule. This is also not a ''major rule'' under the Congressional Review Act (5 U.S.C. 800).

Cost/Benefit Analysis

1. Is there a need for the regulatory action?

SBA's statutory mission is to aid and assist small businesses through a variety of financial, procurement, business development, and advocacy programs. To assist the intended beneficiaries of these programs effectively, SBA must establish distinct definitions of which businesses are deemed small businesses. The Small Business Act (15 U.S.C. 632(a)) (Act) delegates to the SBA Administrator the responsibility for establishing small business definitions. The Act also requires that small business definitions vary from industry to industry to reflect industry differences. The supplementary information to this interim final rule explains how SBA adjusts size standards for inflation. SBA is required to assess the impact of inflation on its monetary-based size standards at least once every 5 years (67 FR 3041 (January 23, 2002) and 13 CFR 121.102(c)). Many businesses may have lost small business eligibility for Federal assistance under SBA's monetary-based size standards simply because of inflation that has occurred since the last inflation adjustment to size standards in 2014. This interim final rule aims to make those businesses eligible again for Federal assistance.

2. What are the potential benefits and costs of this regulatory action?

The most significant benefit of this interim final rule is to enable businesses that have exceeded size standards simply due to inflation-driven revenue growth to regain eligibility for Federal small business assistance programs. This will also help businesses about to

exceed their size standards to retain small business eligibility for Federal programs for a longer period. These programs include SBA's financial assistance programs, economic injury disaster loans, and Federal procurement programs intended for small businesses. Federal procurement programs provide targeted opportunities for small businesses under SBA's business development programs, such as 8(a), Small Disadvantaged Businesses (SDB), small businesses located in Historically Underutilized Business Zones (HUBZone), women-owned small businesses (WOSB), economically disadvantaged women-owned small businesses (EDWOSB), and service-disabled veteran-owned small businesses (SDVOSB). Federal agencies may also use SBA's size standards for a variety of other regulatory and program purposes. These programs assist small businesses to become more knowledgeable, stable, and competitive.

Besides small business contracting opportunities and financial assistance, small businesses also benefit from reduced fees, less paperwork, and fewer compliance requirements that are available to small businesses through Federal agencies that use SBA's monetary-based size standards.

The Baseline

OMB directs agencies to establish an appropriate baseline to evaluate the benefits, costs, and/or transfer impacts of regulatory actions, as well as discuss the alternative approaches considered, if any. The baseline should represent the agency's best assessment of what the world would look like absent the regulatory action. For a new regulatory action modifying an existing regulation (such as adjusting the existing size standards for inflation), a baseline assuming no change to the regulation (*i.e.,* maintaining the status quo) generally provides an appropriate benchmark for evaluating benefits, costs, or transfer impacts of proposed regulatory changes and their alternatives.

Based on the 2012 Economic Census (*https://www2.census.gov/econ2012/EC/*) special tabulations (the latest available and compiled from a special tabulation provided by the U.S. Census Bureau), 2012 County Business Patterns Reports (*https://www.census.gov/programs-surveys/cbp.html*) (for industries not covered by the Economic Census), and 2012 Agricultural Census (*https://www.nass.usda.gov/*) tabulations (for agricultural industries), of a total of about 7.2 million firms in all industries with receipts-based size standards, 96.2 percent are considered small and 3.8 percent are considered other than small under the current size standards. Similarly, based on the fourth quarter of 2018 data from the Federal Deposit Insurance Corporation (FDIC), available at *https://www5.fdic.gov/sdi/download_large_list_outside.asp,* and the National Credit Union Administration (NCUA), available at *https://www.ncua.gov/analysis/credit-union-corporate-call-report-data/quarterly-data,* of about 13,600 total firms subject to the assets-based size standards, 83 percent were considered small.

Based on the data from the Federal Procurement Data System—Next Generation (FPDS–NG) for fiscal years 2015–2017, available at *https://www.fpds.gov,* on average, about 88,700 unique firms in industries subject to monetary-based size standards received at least one Federal contract during that period. Of those 88,700 firms, 83 percent were small. Businesses subject to monetary-based standards received $182 billion in annual average Federal contract dollars during that period, of which $63.7 billion or about 35 percent went to small businesses. Of total dollars awarded to small businesses subject to monetary-based size standards, $45 billion, or 71 percent, was awarded through various small business set-aside programs and the other 29 percent was awarded through non-set aside contracts.

Based on the SBA's internal data on its loan programs, small businesses subject to monetary-based size standards received, on an annual basis, a total of nearly 58,600 7(a) and 504 loans for fiscal years 2016–2018, totaling $24.5 billion, of which 85 percent was issued through the 7(a) program and 15 percent was issued through the 504/CDC program. During fiscal year 2018, small businesses in those industries also received about 11,350 loans through the SBA's Economic Injury Disaster Loan (EIDL) program, totaling about $1.0 billion on an annual basis. Table 3, ''Impact Analysis Inflation Adjustment to Monetary-based Size Standards,'' provides these baseline results.

TABLE 3—IMPACT ANALYSIS INFLATION ADJUSTMENT TO MONETARY-BASED SIZE STANDARDS

Factor	Current (baseline)	After inflation adjustment	Percent change
Total firms subject to monetary-based size standard (million)—2012 Economic Census	7.18	7.18	0.0
Total small firms subject to monetary-based standard (million)—2012 Economic Census	6.91	7.00	1.3
Total small firms as % of total firms—2012 Economic Census	96.2	97.4	1.2
Total small firms share (%) of industry receipts for receipt-based size standards	29.0	29.7	0.7
Total small firms share (%) of industry assets for assets-based size standards	5.6	6.0	0.4
Average total number of unique firms with monetary-based size standards getting Federal contracts—FPDS–NG (2015–2017)	88,700	88,700	0.0
Average total number of unique small firms with monetary-based size standards getting Federal contracts—FPDS–NG (2015–2017)	73,825	74,706	1.2
Unique small firms as % with monetary-based size standards getting Federal contracts	83.2	84.2	1.2
Average total contract dollars awarded to business concerns, subject to monetary-based standards ($ billion)—FPDS–NG (2015–2017)	$182.1	$182.1	0.0
Average total small business contract dollars awarded to businesses subject to monetary-based size standard ($ billion)—FPDS–NG (2015–2017)	$63.7	$64.4	1.1
Small business dollars as % of total dollars awarded to firms subject to monetary-based standards	34.9	35.3	1.1
Annual average number of 7(a) and 504 loans to businesses subject to monetary-based standards (2015–2018)	58,569	58,685	0.2
Annual average amount of 7(a) and 504 loans awarded issued to firms subject to monetary-based standard ($ billion) (2015–2018)	$24.5	$24.6	0.2

TABLE 3—IMPACT ANALYSIS INFLATION ADJUSTMENT TO MONETARY-BASED SIZE STANDARDS—Continued

Factor	Current (baseline)	After inflation adjustment	Percent change
Number of EIDL loans to businesses subject to monetary-based size standards (2018)	11,345	11,376	0.3
Amount of EIDL loans ($ million)	$1,011	$1,014	0.3

Benefits

The most significant benefits to businesses from the adjustment of size standards for include: (1) Some businesses that are above the current size standards may gain small business status under the higher, inflation-adjusted size standards, thereby enabling them to participate in Federal small business assistance programs; (2) growing small businesses that are close to exceeding the current size standards will be able to retain their small business status under the higher size standards, thereby enabling them to continue their participation in the programs; and (3) Federal agencies will have a larger pool of small businesses from which to draw for their small business procurement programs.

SBA estimates that this inflation adjustment will enable approximately 89,730 firms in industries and subindustries with receipts-based size standards and about 161 firms in industries with assets-based size standards that are currently above SBA's size standards to gain small business status and become eligible for these programs. This represents a total of 89,891 additional firms that would qualify as small business under the inflation-adjusted size standards. This will increase the small business share of total receipts in industries and subindustries with receipts-based size standards from 29.0 percent to 29.7 percent, and the small business share of total assets in industries with assets-based size standards from 5.7 percent to 6.0 percent.

Based on FPDS–NG data from fiscal years 2015–2017, SBA estimates that firms gaining small business status under the inflation-adjusted size standards could receive between $700 million and $750 million in additional small business Federal contract dollars. This represents an increase of about 1.2 percent over the baseline. The added competition for many of these procurements could also result in lower prices to the Government for procurements reserved for small businesses, but SBA cannot quantify this benefit. Additionally, by allowing businesses above the size threshold to regain small business status and advanced small businesses close to size standards to prolong their small status for a longer period, this interim final rule could also expand the pool of qualified small firms for agencies to draw upon to meet their small business procurement requirements.

Based on the fiscal years 2016–2018 SBA loan data, SBA estimates about 115–120 additional loans totaling between $60 million and $65 million could be made to these newly defined small businesses under SBA's 7(a) and 504 Loan Programs under the adjusted size standards. Higher inflation-adjusted size standards will likely result in more small business guaranteed loans to businesses in these industries, but it is impractical to try to estimate the exact number and total amount of loans. There are two reasons for this: (1) Under the Jobs Act, SBA can now guarantee substantially larger loans than in the past; and (2) as described above, the Jobs Act established an alternative size standard ($15 million in tangible net worth and $5 million in net income after income taxes) for business concerns that do not meet the size standards for their industry. Therefore, SBA finds it difficult to quantify the actual impact of these inflation-adjusted size standards on its 7(a) and 504 Loan Programs.

Newly defined small businesses will also benefit from SBA's Economic Injury Disaster Loan (EIDL) Program. Since this program is contingent on the occurrence and severity of a disaster in the future, SBA cannot make a meaningful estimate of this impact. However, based on historical trends, SBA estimates that the EIDL Program could issue about 30 loans per year (a total of about $3 million dollars) to businesses qualifying as small under the inflation-adjusted size standards.

Additionally, the newly defined small businesses would also benefit through reduced fees, less paperwork, and fewer compliance requirements that are available to small businesses through the Federal Government, but SBA has no data to quantify this impact.

Costs

To the extent that those 89,891 additional small firms could become active in Federal procurement programs, the adjusted size standards in this final interim rule may entail some additional administrative costs to the government as a result of the increase in the number of businesses eligible for Federal small business programs. For example, there will be more firms seeking SBA's guaranteed loans; more firms eligible for enrollment in the Dynamic Small Business Search (DSBS) database or at *https://certify.sba.gov;* more firms seeking certification as 8(a) or HUBZone firms; more firms qualifying for small business, WOSB, EDWOSB, SDVOSB, and SDB status; and more firms applying for SBA's 8(a)/BD and All Small Mentor-Protégé programs.

With an expanded pool of businesses eligible for small business assistance under higher size standards due to this inflation adjustment, it is likely that Federal agencies would set aside more contracts for small businesses. One may surmise that this might result in a higher number of small business size protests and additional processing costs to agencies. However, SBA's historical data on size protests shows that the number of size protests actually decreased after an increase in the number businesses qualifying as small as a result of size standards revisions as part of the first 5-year review of size standards completed in early 2016. Specifically, on an annual basis, the number of size protests dropped from about 600 during fiscal years 2011–2013 (review of most receipts-based size standards was completed by the end of FY 2013) to about 500 during fiscal years 2014–2016. Similarly, among those newly defined small businesses seeking SBA's loans, there could be some additional costs associated with compliance and verification of their small business status. However, small business lenders have an option of using the tangible net worth and net income-based alternative size standard instead of using the industry-based size standards to establish eligibility for SBA's loans. For all these reasons, SBA believes that these added administrative costs will be minor because necessary mechanisms are already in place to handle these added requirements.

Among those newly defined small businesses seeking SBA's assistance, there could be some additional costs

associated with compliance and verification of small business status and protests of small business status. However, SBA believes that these added administrative costs will be minimal because mechanisms are already in place to handle these requirements.

In some cases, Federal Government contracts may have higher costs. With a greater number of businesses defined as small, Federal agencies may choose to set aside more contracts for competition among small businesses only rather than using full and open competition. The movement from unrestricted to small business set-aside contracting might result in competition among fewer total bidders, although there will be more small businesses eligible to submit offers. However, the additional costs associated with fewer bidders are expected to be minor since, by law, procurements may be set aside for small businesses or reserved for the 8(a), HUBZone, WOSB, EDWOSB, or SDVOSB Programs only if awards are expected to be made at fair and reasonable prices.

In addition, there may be higher costs when more full and open contracts are awarded to HUBZone businesses that receive price evaluation preferences. However, with agencies likely setting aside more contracts for small businesses in response to a larger pool of small businesses under inflation-adjusted higher size standards, HUBZone firms may receive more set-aside contracts and fewer full and open contracts, thereby resulting in some cost savings to agencies. SBA cannot estimate such costs savings because it is impossible to determine the number and value of unrestricted contracts to be otherwise awarded to HUBZone firms that will be awarded as set-asides. However, such cost savings are likely to be relatively small, as only a small fraction of full and open contracts are awarded to HUBZone businesses.

Transfer Impacts

The size standards adjustments in this interim final rule may have some distributional effects among large and small businesses. Although SBA cannot estimate with certainty the actual outcome of the gains and losses among small and large businesses, it can identify several probable impacts. With an expanded pool of small businesses available under the higher inflation-adjusted size standards, there may be a transfer of some Federal contracts to small businesses from large businesses. Large businesses may have fewer Federal contract opportunities as Federal agencies decide to set aside more contracts for small businesses.

Similarly, some businesses defined as small under the current size standards may obtain fewer Federal contracts due to the increased competition from more businesses defined as small under the higher inflation-adjusted size standards. This transfer may be offset by a greater number of Federal procurements set aside for all small businesses. The number of newly defined and expanding small businesses that are willing and able to sell to the Federal Government will limit the potential transfer of contracts from large and currently defined small businesses. SBA cannot estimate the potential distributional impacts of these transfers with any degree of precision.

The adjustment for inflation to monetary-based industry and program-specific size standards is consistent with SBA's statutory mandate to assist small business. This regulatory action promotes the Administration's objectives. One of SBA's goals in support of the Administration's objectives is to help individual small businesses succeed through fair and equitable access to capital and credit, Government contracts, and management and technical assistance. Reviewing and modifying size standards when appropriate, including periodic inflation adjustments, ensures that intended beneficiaries have access to small business programs designed to assist them.

Executive Order 13563

Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A description of the need for this regulatory action and benefits and costs associated with this action, including possible distributional impacts that relate to Executive Order 13563, is included above in the Cost/Benefit Analysis under Executive Order 12866. Additionally, by reviewing and adjusting size standards for inflation, SBA is complying with section 6 of Executive Order 13563, which calls for retrospective analyses of existing rules.

During its March 26, 2019 and April 23, 2019 meetings, SBA updated the Small Business Procurement Advisory Council (SBPAC) on its upcoming size standards rules, including this inflation adjustment rule. On April 18, 2019, SBA also presented a similar update to the small business audience at the 2019 Annual Government Procurement Conference.

Additionally, SBA issued a revised ''Size Standards Methodology'' white paper and published a notification in the April 27, 2018 issue of the **Federal Register** (83 FR 18468) to advise the public that the document was available for public review and comments. The ''Size Standards Methodology'' white paper explains how SBA establishes, reviews, and modifies its receipts-based and employee-based small business size standards. The white paper also describes how SBA adjusts size standards for inflation and updates its table of size standards when OMB revises the NAICS codes every 5 years. On April 11, 2019, SBA published a **Federal Register** notification (84 FR 14587) advising the public that the Agency had issued a revised final ''Size Standards Methodology'' white paper.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. This rule does not have retroactive or preemptive effect.

Executive Order 13132

For purposes of Executive Order 13132, SBA has determined that this interim final rule will not have substantial, direct effects on the States, on the relationship between the National government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, SBA has determined that this interim final rule has no federalism implications warranting preparation of a federalism assessment.

Executive Order 13771

This rule is not expected to be an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Paperwork Reduction Act

For the purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this interim final rule will not impose any new reporting or recordkeeping requirements.

Regulatory Flexibility Act

According to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, when an agency issues a rulemaking, it must prepare a regulatory flexibility analysis to address the impact of the rule on small entities.

Initial Regulatory Flexibility Analysis

Under the Regulatory Flexibility Act (RFA), this interim final rule may have a significant impact on a substantial number of small businesses in the industries and subindustries with

monetary-based size standards. As described above, this rule may affect small businesses in those industries seeking Federal contracts, loans under SBA's 7(a), 504, and Economic Injury Disaster Loan Programs, and assistance under other Federal small business programs.

Immediately below, SBA sets forth an initial regulatory flexibility analysis (IRFA) for this interim final rule to address the following questions: (1) What is the need for and objective of the rule?; (2) What are SBA's description and estimate for the number of small businesses to which the rule will apply?; (3) What are the projected reporting, recordkeeping, and other compliance requirements of the rule?; (4) What are the relevant Federal rules that may duplicate, overlap, or conflict with the rule?; and (5) What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small businesses?

1. What is the need for and objective of the rule?

As discussed above, this revision to monetary-based size standards to account for inflation will more appropriately define small businesses. This interim final rule merely restores small business eligibility in real terms to businesses that have grown above the existing size standard due to inflation-led revenue growth rather than due to increased business activity.

Section 3(a) of the Small Business Act (15 U.S.C. 632(a)) gives SBA the authority to establish and change size standards. Within its administrative discretion, SBA implemented a policy in its regulations to review the effect of inflation on size standards at least once every 5 years (13 CFR 121.102(c)) and make any changes as appropriate. A review of the latest data indicates that inflation has increased a sufficient amount since the 2014 adjustment, enough to warrant another inflation adjustment to the current monetary-based size standards. As discussed above, adjusting size standards for inflation is also consistent with SBA's statutory requirement to review all size standards and make necessary adjustments to reflect current market conditions every 5 years.

2. What are SBA's description and estimate for the number of small businesses to which the rule will apply?

As discussed above, based on the 2012 Economic Census tabulations, SBA estimates that about 89,730 additional firms will become small because of this adjustment to the receipts-based size standards of 518 industries and 8 subindustries. That represents 1.3 percent of the total number of firms that are small under current monetary-based size standards. This will result in an increase in the small business share of total industry receipts in those industries and subindustries from 29.0 percent under the current size standards to 29.7 percent under the inflation-adjusted size standards. Due to the adjustment of assets-based size standards in 5 industries, about 160 additional firms will gain small business status in those industries. This will increase the small business share of total assets in those industries from 5.7 percent to 6.0 percent. The size standards adopted in this interim final rule will enable businesses that have exceeded the size standards for their industries to regain small business status. It will also help currently small businesses retain their small business status for a longer period. Many firms may have lost their eligibility and find it difficult to compete at current size standards with companies that are significantly larger than they are. SBA believes the competitive impact will be positive for existing small businesses and for those that exceed the size standards but are on the very low end of those that are not small. They might otherwise be called or referred to as mid-sized businesses, although SBA only defines what is small; entities that are not small are ''other than small.''

3. What are the projected reporting, recordkeeping, and other compliance requirements of the rule?

The inflation adjustment to size standards imposes no additional reporting or recordkeeping requirements on small businesses. However, qualifying for Federal procurement and several other programs requires that businesses register in the System for Award Management (SAM) database and certify in SAM that they are small annually. Therefore, newly eligible small businesses opting to participate in those programs must comply with SAM requirements. Businesses whose status changes in SAM from other than small to small must update their SAM profiles and complete the ''representations and certifications'' section of SAM. However, there are no costs associated with SAM registration or certification. Changing size standards alters access to SBA's programs but it does not impose a regulatory burden because it neither regulates nor controls business behavior.

4. What are the relevant Federal rules which may duplicate, overlap, or conflict with the rule?

Under section 3(a)(2)(C) of the Small Business Act, 15 U.S.C. 632(a)(2)(c), Federal agencies must use SBA's size standards to define a small business, unless specifically authorized by statute to do otherwise. In 1995, SBA published in the **Federal Register** a list of statutory and regulatory size standards that identified the application of SBA's size standards as well as other size standards used by Federal agencies (60 FR 57988 (November 24, 1995)). SBA is not aware of any Federal rule that would duplicate or conflict with establishing size standards.

However, the Small Business Act and SBA's regulations allow Federal agencies to develop different size standards with the approval of SBA's Administrator if they believe that SBA's size standards are not appropriate for their programs (13 CFR 121.903). The Regulatory Flexibility Act authorizes an Agency to establish an alternative small business definition for Regulatory Flexibility Analysis purposes, after consultation with the Office of Advocacy of the U.S. Small Business Administration (5 U.S.C. 601(3)).

5. What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small entities?

By law, SBA is required to develop numerical size standards for establishing eligibility for Federal small business assistance programs. Other than varying size standards by industry and changing the measures SBA uses to calculate business size (*i.e.,* number of employees vs. annual receipts), no practical alternative exists to the system of numerical size standards.

SBA's only other consideration was whether not to adjust current size standards for the inflation. However, SBA believes that the 8.37 percent inflation increase that has occurred since the previous inflation adjustment in June 2014 (and the 40.26 percent inflation increase that has occurred since 2000, when the current $750,000 agricultural size standard was established by statute) sufficiently affects the real value of size standards to warrant applying an increase at this time.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs—business, Individuals with disabilities, Loan programs—business, Reporting

and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, SBA amends 13 CFR part 121 as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 662, and 694a(9).

■ 2. In § 121.201, amend the table ''Small Business Size Standards by NAICS Industry'' as follows:

■ a. Revise Subsectors 111 and 112, entries ''113110'' and ''113210'', Subsectors 114 and 115, entries ''213112'' through ''213115'', ''221310'', ''221320'', and ''221330'', Subsectors 236 through 238, entries ''441120'', ''441210'', ''441222'', ''441228'', ''441310'', and ''441320'', Subsectors 442 through 448 and 451 through 453, entries ''454110'', ''454210'', ''454390'', and ''481219'', Subsectors 484 and 485, entries ''486210'' and ''486990'', Subsectors 487, 488, and 491, entry ''492210'', Subsector 493, entries ''511210'', ''512110'', ''512120'', ''512131'', ''512132'', ''512191'', ''512199'', ''512240'', and ''512290'', Subsector 515, entries ''517410'' and ''517919'', Subsector 518, entries ''519110'', ''519120'', and ''519190'', Subsectors 522 and 523, entries ''524113'', ''524114'', ''524127'', ''524128'', ''524130'', ''524210'', ''524291'', ''524292'', and ''524298'', Subsectors 525 and 531 through 533, entries ''541110'', ''541191'', ''541199'', ''541211'', ''541213'', ''541214'', ''541219'', ''541310'', ''541320'', ''541330'', ''541330 first, second and third sub-entry'', ''541340'', ''541350'', ''541360'', ''541370'', ''541380'', ''541410'', ''541420'', ''541430'', ''541490'', ''541511'' through ''541513'', ''541519'', ''541519 sub-entry'', ''541611'', ''541612'' through ''541614'', ''541618'', ''541620'', ''541690'', ''541720'', ''541810'', ''541820'', ''541830'', ''541840'', ''541850'', ''541860'', ''541870'', ''541890'', ''541910'', ''541921'', ''541922'', ''541930'', ''541940'', and ''541990'', Subsectors 551, 561, 562, 611, 621 through 624, 711 through 713, 721, 722, and 811 through 813.

■ b. Revise footnote 9.

The revisions read as follows:

§ 121.201 What size standards has SBA identified by North American Industry Classification System codes?

* * * * *

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
	Sector 11—Agriculture, Forestry, Fishing and Hunting		
	Subsector 111—Crop Production		
111110	Soybean Farming	$1.0	
111120	Oilseed (except Soybean) Farming	$1.0	
111130	Dry Pea and Bean Farming	$1.0	
111140	Wheat Farming	$1.0	
111150	Corn Farming	$1.0	
111160	Rice Farming	$1.0	
111191	Oilseed and Grain Combination Farming	$1.0	
111199	All Other Grain Farming	$1.0	
111211	Potato Farming	$1.0	
111219	Other Vegetable (except Potato) and Melon Farming	$1.0	
111310	Orange Groves	$1.0	
111320	Citrus (except Orange) Groves	$1.0	
111331	Apple Orchards	$1.0	
111332	Grape Vineyards	$1.0	
111333	Strawberry Farming	$1.0	
111334	Berry (except Strawberry) Farming	$1.0	
111335	Tree Nut Farming	$1.0	
111336	Fruit and Tree Nut Combination Farming	$1.0	
111339	Other Noncitrus Fruit Farming	$1.0	
111411	Mushroom Production	$1.0	
111419	Other Food Crops Grown Under Cover	$1.0	
111421	Nursery and Tree Production	$1.0	
111422	Floriculture Production	$1.0	
111910	Tobacco Farming	$1.0	
111920	Cotton Farming	$1.0	
111930	Sugarcane Farming	$1.0	
111940	Hay Farming	$1.0	
111991	Sugar Beet Farming	$1.0	
111992	Peanut Farming	$1.0	
111998	All Other Miscellaneous Crop Farming	$1.0	
	Subsector 112—Animal Production and Aquaculture		
112111	Beef Cattle Ranching and Farming	$1.0	
112112	Cattle Feedlots	$8.0	
112120	Dairy Cattle and Milk Production	$1.0	
112210	Hog and Pig Farming	$1.0	
112310	Chicken Egg Production	$16.5	
112320	Broilers and Other Meat Type Chicken Production	$1.0	
112330	Turkey Production	$1.0	
112340	Poultry Hatcheries	$1.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
112390	Other Poultry Production	$1.0	
112410	Sheep Farming	$1.0	
112420	Goat Farming	$1.0	
112511	Finfish Farming and Fish Hatcheries	$1.0	
112512	Shellfish Farming	$1.0	
112519	Other Aquaculture	$1.0	
112910	Apiculture	$1.0	
112920	Horse and Other Equine Production	$1.0	
112930	Fur-Bearing Animal and Rabbit Production	$1.0	
112990	All Other Animal Production	$1.0	
	Subsector 113—Forestry and Logging		
113110	Timber Tract Operations	$12.0	
113210	Forest Nurseries and Gathering of Forest Products	$12.0	
*	* * * * *	*	*
	Subsector 114—Fishing, Hunting and Trapping		
114111	Finfish Fishing	$22.0	
114112	Shellfish Fishing	$6.0	
114119	Other Marine Fishing	$8.0	
114210	Hunting and Trapping	$6.0	
	Subsector 115—Support Activities for Agriculture and Forestry		
115111	Cotton Ginning	$12.0	
115112	Soil Preparation, Planting, and Cultivating	$8.0	
115113	Crop Harvesting, Primarily by Machine	$8.0	
115114	Postharvest Crop Activities (except Cotton Ginning)	$30.0	
115115	Farm Labor Contractors and Crew Leaders	$16.5	
115116	Farm Management Services	$8.0	
115210	Support Activities for Animal Production	$8.0	
115310	Support Activities for Forestry	$8.0	
115310 (Exception 1)	Forest Fire Suppression [17]	$20.5 [17]	
115310 (Exception 2)	Fuels Management Services [17]	$20.5 [17]	
	Sector 21—Mining, Quarrying, and Oil and Gas Extraction		
*	* * * * *	*	*
	Subsector 213—Support Activities for Mining		
*	* * * * *	*	*
213112	Support Activities for Oil and Gas Operations	$41.5	
213113	Support Activities for Coal Mining	$22.0	
213114	Support Activities for Metal Mining	$22.0	
213115	Support Activities for Nonmetallic Minerals (except Fuels)	$8.0	
	Sector 22—Utilities **Subsector 221—Utilities**		
*	* * * * *	*	*
221310	Water Supply and Irrigation Systems	$30.0	
221320	Sewage Treatment Facilities	$22.0	
221330	Steam and Air-Conditioning Supply	$16.5	
	Sector 23—Construction **Subsector 236—Construction of Buildings**		
236115	New Single-family Housing Construction (Except For-Sale Builders)	$39.5	
236116	New Multifamily Housing Construction (except For-Sale Builders)	$39.5	
236117	New Housing For-Sale Builders	$39.5	
236118	Residential Remodelers	$39.5	
236210	Industrial Building Construction	$39.5	
236220	Commercial and Institutional Building Construction	$39.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
	Subsector 237—Heavy and Civil Engineering Construction		
237110	Water and Sewer Line and Related Structures Construction	$39.5	
237120	Oil and Gas Pipeline and Related Structures Construction	$39.5	
237130	Power and Communication Line and Related Structures Construction	$39.5	
237210	Land Subdivision	$30.0	
237310	Highway, Street, and Bridge Construction	$39.5	
237990	Other Heavy and Civil Engineering Construction	$39.5	
237900 (Exception)	Dredging and Surface Cleanup Activities [2]	$30.0 [2]	
	Subsector 238—Specialty Trade Contractors		
238110	Poured Concrete Foundation and Structure Contractors	$16.5	
238120	Structural Steel and Precast Concrete Contractors	$16.5	
238130	Framing Contractors	$16.5	
238140	Masonry Contractors	$16.5	
238150	Glass and Glazing Contractors	$16.5	
238160	Roofing Contractors	$16.5	
238170	Siding Contractors	$16.5	
238190	Other Foundation, Structure, and Building Exterior Contractors	$16.5	
238210	Electrical Contractors and Other Wiring Installation Contractors	$16.5	
238220	Plumbing, Heating, and Air-Conditioning Contractors	$16.5	
238290	Other Building Equipment Contractors	$16.5	
238310	Drywall and Insulation Contractors	$16.5	
238320	Painting and Wall Covering Contractors	$16.5	
238330	Flooring Contractors	$16.5	
238340	Tile and Terrazzo Contractors	$16.5	
238350	Finish Carpentry Contractors	$16.5	
238390	Other Building Finishing Contractors	$16.5	
238910	Site Preparation Contractors	$16.5	
238990	All Other Specialty Trade Contractors	$16.5	
238990 (Exception)	Building and Property Specialty Trade Services [13]	$16.5 [13]	
*	* * * * * *	*	*
	Sector 44–45—Retail Trade		
*	* * * * * *	*	*
	Subsector 441—Motor Vehicle and Parts Dealers		
*	* * * * * *	*	*
441120	Used Car Dealers	$27.0	
441210	Recreational Vehicle Dealers	$35.0	
441222	Boat Dealers	$35.0	
441228	Motorcycle, ATV, and All Other Motor Vehicle Dealers	$35.0	
441310	Automotive Parts and Accessories Stores	$16.5	
441320	Tire Dealers	$16.5	
	Subsector 442—Furniture and Home Furnishings Stores		
442110	Furniture Stores	$22.0	
442210	Floor Covering Stores	$8.0	
442291	Window Treatment Stores	$8.0	
442299	All Other Home Furnishings Stores	$22.0	
	Subsector 443—Electronics and Appliance Stores		
443141	Household Appliance Stores	$12.0	
443142	Electronics Stores	$35.0	
	Subsector 444—Building Material and Garden Equipment and Supplies Dealers		
444110	Home Centers	$41.5	
444120	Paint and Wallpaper Stores	$30.0	
444130	Hardware Stores	$8.0	
444190	Other Building Material Dealers	$22.0	
444210	Outdoor Power Equipment Stores	$8.0	
444220	Nursery and Garden Centers	$12.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
	Subsector 445—Food and Beverage Stores		
445110	Supermarkets and Other Grocery (except Convenience) Stores	$35.0	
445120	Convenience Stores	$32.0	
445210	Meat Markets	$8.0	
445220	Fish and Seafood Markets	$8.0	
445230	Fruit and Vegetable Markets	$8.0	
445291	Baked Goods Stores	$8.0	
445292	Confectionery and Nut Stores	$8.0	
445299	All Other Specialty Food Stores	$8.0	
445310	Beer, Wine and Liquor Stores	$8.0	
	Subsector 446—Health and Personal Care Stores		
446110	Pharmacies and Drug Stores	$30.0	
446120	Cosmetics, Beauty Supplies and Perfume Stores	$30.0	
446130	Optical Goods Stores	$22.0	
446191	Food (Health) Supplement Stores	$16.5	
446199	All Other Health and Personal Care Stores	$8.0	
	Subsector 447—Gasoline Stations		
447110	Gasoline Stations with Convenience Stores	$32.0	
447190	Other Gasoline Stations	$16.5	
	Subsector 448—Clothing and Clothing Accessories Stores		
448110	Men's Clothing Stores	$12.0	
448120	Women's Clothing Stores	$30.0	
448130	Children's and Infants' Clothing Stores	$35.0	
448140	Family Clothing Stores	$41.5	
448150	Clothing Accessories Stores	$16.5	
448190	Other Clothing Stores	$22.0	
448210	Shoe Stores	$30.0	
448310	Jewelry Stores	$16.5	
448320	Luggage and Leather Goods Stores	$30.0	
	Subsector 451—Sporting Good, Hobby, Book and Music Stores		
451110	Sporting Goods Stores	$16.5	
451120	Hobby, Toy and Game Stores	$30.0	
451130	Sewing, Needlework and Piece Goods Stores	$30.0	
451140	Musical Instrument and Supplies Stores	$12.0	
451211	Book Stores	$30.0	
451212	News Dealers and Newsstands	$8.0	
	Subsector 452—General Merchandise Stores		
452210	Department Stores	$35.0	
452311	Warehouse Clubs and Superstores	$32.0	
452319	All Other General Merchandise Stores	$35.0	
	Subsector 453—Miscellaneous Store Retailers		
453110	Florists	$8.0	
453210	Office Supplies and Stationery Stores	$35.0	
453220	Gift, Novelty and Souvenir Stores	$8.0	
453310	Used Merchandise Stores	$8.0	
453910	Pet and Pet Supplies Stores	$22.0	
453920	Art Dealers	$8.0	
453930	Manufactured (Mobile) Home Dealers	$16.5	
453991	Tobacco Stores	$8.0	
453998	All Other Miscellaneous Store Retailers (except Tobacco Stores)	$8.0	
	Subsector 454—Nonstore Retailers		
454110	Electronic Shopping and Mail-Order Houses	$41.5	
454210	Vending Machine Operators	$12.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
454390	Other Direct Selling Establishments	$8.0	
	Sector 48–49—Transportation and Warehousing		
	Subsector 481—Air Transportation		
*	* * * * *	*	*
481219	Other Nonscheduled Air Transportation	$16.5	
*	* * * * *	*	*
	Subsector 484—Truck Transportation		
484110	General Freight Trucking, Local	$30.0	
484121	General Freight Trucking, Long-Distance, Truckload	$30.0	
484122	General Freight Trucking, Long-Distance, Less Than Truckload	$30.0	
484210	Used Household and Office Goods Moving	$30.0	
484220	Specialized Freight (except Used Goods) Trucking, Local	$30.0	
484230	Specialized Freight (except Used Goods) Trucking, Long-Distance	$30.0	
	Subsector 485—Transit and Ground Passenger Transportation		
485111	Mixed Mode Transit Systems	$16.5	
485112	Commuter Rail Systems	$16.5	
485113	Bus and Other Motor Vehicle Transit Systems	$16.5	
485119	Other Urban Transit Systems	$16.5	
485210	Interurban and Rural Bus Transportation	$16.5	
485310	Taxi Service	$16.5	
485320	Limousine Service	$16.5	
485410	School and Employee Bus Transportation	$16.5	
485510	Charter Bus Industry	$16.5	
485991	Special Needs Transportation	$16.5	
485999	All Other Transit and Ground Passenger Transportation	$16.5	
	Subsector 486—Pipeline Transportation		
*	* * * * *	*	*
486210	Pipeline Transportation of Natural Gas	$30.0	
*	* * * * *	*	*
486990	All Other Pipeline Transportation	$40.5	
	Subsector 487—Scenic and Sightseeing Transportation		
487110	Scenic and Sightseeing Transportation, Land	$8.0	
487210	Scenic and Sightseeing Transportation, Water	$8.0	
487990	Scenic and Sightseeing Transportation, Other	$8.0	
	Subsector 488—Support Activities for Transportation		
488111	Air Traffic Control	$35.0	
488119	Other Airport Operations	$35.0	
488190	Other Support Activities for Air Transportation	$35.0	
488210	Support Activities for Rail Transportation	$16.5	
488310	Port and Harbor Operations	$41.5	
488320	Marine Cargo Handling	$41.5	
488330	Navigational Services to Shipping	$41.5	
488390	Other Support Activities for Water Transportation	$41.5	
488410	Motor Vehicle Towing	$8.0	
488490	Other Support Activities for Road Transportation	$8.0	
488510	Freight Transportation Arrangement [10]	$16.5 [10]	
488510 (Exception)	Non-Vessel Owning Common Carriers and Household Goods Forwarders	$30.0	
488991	Packing and Crating	$30.0	
488999	All Other Support Activities for Transportation	$8.0	
	Subsector 491—Postal Service		
491110	Postal Service	$8.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
	Subsector 492—Couriers and Messengers		
*	* * * * *	*	*
492210	Local Messengers and Local Delivery	$30.0	
	Subsector 493—Warehousing and Storage		
493110	General Warehousing and Storage	$30.0	
493120	Refrigerated Warehousing and Storage	$30.0	
493130	Farm Product Warehousing and Storage	$30.0	
493190	Other Warehousing and Storage	$30.0	
	Sector 51—Information **Subsector 511—Publishing Industries (except Internet)**		
*	* * * * *	*	*
511210	Software Publishers [20]	$41.5 [20]	
	Subsector 512—Motion Picture and Sound Recording Industries		
512110	Motion Picture and Video Production	$35.0	
512120	Motion Picture and Video Distribution	$34.5	
512131	Motion Picture Theaters (except Drive-Ins)	$41.5	
512132	Drive-In Motion Picture Theaters	$8.0	
512191	Teleproduction and Other Postproduction Services	$34.5	
512199	Other Motion Picture and Video Industries	$22.0	
*	* * * * *	*	*
512240	Sound Recording Studios	$8.0	
*	* * * * *	*	*
512290	Other Sound Recording Industries	$12.0	
	Subsector 515—Broadcasting (except Internet)		
515111	Radio Networks	$35.0	
515112	Radio Stations	$41.5	
515120	Television Broadcasting	$41.5	
515210	Cable and Other Subscription Programming	$41.5	
	Subsector 517—Telecommunications		
*	* * * * *	*	*
517410	Satellite Telecommunications	$35.0	
*	* * * * *	*	*
517919	All Other Telecommunications	$35.0	
	Subsector 518—Data Processing, Hosting, and Related Services		
518210	Data Processing, Hosting, and Related Services	$35.0	
	Subsector 519—Other Information Services		
519110	News Syndicates	$30.0	
519120	Libraries and Archives	$16.5	
*	* * * * *	*	*
519190	All Other Information Services	$30.0	
	Sector 52—Finance and Insurance **Subsector 522—Credit Intermediation and Related Activities**		
522110	Commercial Banking [8]	$600 million in assets [8].	
522120	Savings Institutions [8]	$600 million in assets [8].	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
522130	Credit Unions [8]	$600 million in assets [8].	
522190	Other Depository Credit Intermediation [8]	$600 million in assets [8].	
522210	Credit Card Issuing [8]	$600 million in assets [8].	
522220	Sales Financing	$41.5	
522291	Consumer Lending	$41.5	
522292	Real Estate Credit	$41.5	
522293	International Trade Financing	$41.5	
522294	Secondary Market Financing	$41.5	
522298	All Other Nondepository Credit Intermediation	$41.5	
522310	Mortgage and Nonmortgage Loan Brokers	$8.0	
522320	Financial Transactions Processing, Reserve, and Clearinghouse Activities	$41.5	
522390	Other Activities Related to Credit Intermediation	$22.0	
	Subsector 523—Securities, Commodity Contracts, and Other Financial Investments and Related Activities		
523110	Investment Banking and Securities Dealing	$41.5	
523120	Securities Brokerage	$41.5	
523130	Commodity Contracts Dealing	$41.5	
523140	Commodity Contracts Brokerage	$41.5	
523210	Securities and Commodity Exchanges	$41.5	
523910	Miscellaneous Intermediation	$41.5	
523920	Portfolio Management	$41.5	
523930	Investment Advice	$41.5	
523991	Trust, Fiduciary and Custody Activities	$41.5	
523999	Miscellaneous Financial Investment Activities	$41.5	
	Subsector 524—Insurance Carriers and Related Activities		
524113	Direct Life Insurance Carriers	$41.5	
524114	Direct Health and Medical Insurance Carriers	$41.5	
*	* * * * *	*	*
524127	Direct Title Insurance Carriers	$41.5	
524128	Other Direct Insurance (except Life, Health and Medical) Carriers	$41.5	
524130	Reinsurance Carriers	$41.5	
524210	Insurance Agencies and Brokerages	$ 8.0	
524291	Claims Adjusting	$22.0	
524292	Third Party Administration of Insurance and Pension Funds	$35.0	
524298	All Other Insurance Related Activities	$16.5	
	Subsector 525—Funds, Trusts and Other Financial Vehicles		
525110	Pension Funds	$35.0	
525120	Health and Welfare Funds	$35.0	
525190	Other Insurance Funds	$35.0	
525910	Open-End Investment Funds	$35.0	
525920	Trusts, Estates, and Agency Accounts	$35.0	
525990	Other Financial Vehicles	$35.0	
	Sector 53—Real Estate and Rental and Leasing **Subsector 531—Real Estate**		
531110	Lessors of Residential Buildings and Dwellings [9]	$30.0 [9]	
531120	Lessors of Nonresidential Buildings (except Miniwarehouses) [9]	$30.0 [9]	
531130	Lessors of Miniwarehouses and Self-Storage Units [9]	$30.0 [9]	
531190	Lessors of Other Real Estate Property [9]	$30.0 [9]	
531210	Offices of Real Estate Agents and Brokers [10]	$8.0 [10]	
531311	Residential Property Managers	$8.0	
531312	Nonresidential Property Managers	$8.0	
531320	Offices of Real Estate Appraisers	$8.0	
531390	Other Activities Related to Real Estate	$8.0	
	Subsector 532—Rental and Leasing Services		
532111	Passenger Car Rental	$41.5	
532112	Passenger Car Leasing	$41.5	
532120	Truck, Utility Trailer, and RV (Recreational Vehicle) Rental and Leasing	$41.5	
532210	Consumer Electronics and Appliances Rental	$41.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
532281	Formal Wear and Costume Rental	$22.0	
532282	Video Tape and Disc Rental	$30.0	
532283	Home Health Equipment Rental	$35.0	
532284	Recreational Goods Rental	$8.0	
532289	All Other Consumer Goods Rental	$8.0	
532310	General Rental Centers	$8.0	
532411	Commercial Air, Rail, and Water Transportation Equipment Rental and Leasing	$35.0	
532412	Construction, Mining and Forestry Machinery and Equipment Rental and Leasing	$35.0	
532420	Office Machinery and Equipment Rental and Leasing	$35.0	
532490	Other Commercial and Industrial Machinery and Equipment Rental and Leasing	$35.0	
	Subsector 533—Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)		
533110	Lessors of Nonfinancial Intangible Assets (except Copyrighted Works)	$41.5	
	Sector 54—Professional, Scientific and Technical Services **Subsector 541—Professional, Scientific and Technical Services**		
541110	Offices of Lawyers	$12.0	
541191	Title Abstract and Settlement Offices	$12.0	
541199	All Other Legal Services	$12.0	
541211	Offices of Certified Public Accountants	$22.0	
541213	Tax Preparation Services	$22.0	
541214	Payroll Services	$22.0	
541219	Other Accounting Services	$22.0	
541310	Architectural Services	$8.0	
541320	Landscape Architectural Services	$8.0	
541330	Engineering Services	$16.5	
541330 (Exception 1)	Military and Aerospace Equipment and Military Weapons	$41.5	
541330 (Exception 2)	Contracts and Subcontracts for Engineering Services Awarded Under the National Energy Policy Act of 1992.	$41.5	
541330 (Exception 3)	Marine Engineering and Naval Architecture	$41.5	
541340	Drafting Services	$8.0	
541350	Building Inspection Services	$8.0	
541360	Geophysical Surveying and Mapping Services	$16.5	
541370	Surveying and Mapping (except Geophysical) Services	$16.5	
541380	Testing Laboratories	$16.5	
541410	Interior Design Services	$8.0	
541420	Industrial Design Services	$8.0	
541430	Graphic Design Services	$8.0	
541490	Other Specialized Design Services	$8.0	
541511	Custom Computer Programming Services	$30.0	
541512	Computer Systems Design Services	$30.0	
541513	Computer Facilities Management Services	$30.0	
541519	Other Computer Related Services	$30.0	
541519 (Exception)	Information Technology Value Added Resellers [18]		150 [18]
541611	Administrative Management and General Management Consulting Services	$16.5	
541612	Human Resources Consulting Services	$16.5	
541613	Marketing Consulting Services	$16.5	
541614	Process, Physical Distribution and Logistics Consulting Services	$16.5	
541618	Other Management Consulting Services	$16.5	
541620	Environmental Consulting Services	$16.5	
541690	Other Scientific and Technical Consulting Services	$16.5	
*	* * * * *	*	*
541720	Research and Development in the Social Sciences and Humanities	$22.0	
541810	Advertising Agencies [10]	$16.5 [10]	
541820	Public Relations Agencies	$16.5	
541830	Media Buying Agencies	$16.5	
541840	Media Representatives	$16.5	
541850	Outdoor Advertising	$16.5	
541860	Direct Mail Advertising	$16.5	
541870	Advertising Material Distribution Services	$16.5	
541890	Other Services Related to Advertising	$16.5	
541910	Marketing Research and Public Opinion Polling	$16.5	
541921	Photography Studios, Portrait	$8.0	
541922	Commercial Photography	$8.0	
541930	Translation and Interpretation Services	$8.0	
541940	Veterinary Services	$8.0	
541990	All Other Professional, Scientific and Technical Services	$16.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
	Sector 55—Management of Companies and Enterprises **Subsector 551—Management of Companies and Enterprises**		
551111	Offices of Bank Holding Companies	$22.0	
551112	Offices of Other Holding Companies	$22.0	
	Sector 56—Administrative and Support, Waste Management and Remediation Services **Subsector 561—Administrative and Support Services**		
561110	Office Administrative Services	$8.0	
561210	Facilities Support Services [12]	$41.5 [12]	
561311	Employment Placement Agencies	$30.0	
561312	Executive Search Services	$30.0	
561320	Temporary Help Services	$30.0	
561330	Professional Employer Organizations	$30.0	
561410	Document Preparation Services	$16.5	
561421	Telephone Answering Services	$16.5	
561422	Telemarketing Bureaus and Other Contact Centers	$16.5	
561431	Private Mail Centers	$16.5	
561439	Other Business Service Centers (including Copy Shops)	$16.5	
561440	Collection Agencies	$16.5	
561450	Credit Bureaus	$16.5	
561491	Repossession Services	$16.5	
561492	Court Reporting and Stenotype Services	$16.5	
561499	All Other Business Support Services	$16.5	
561510	Travel Agencies [10]	$22.0 [10]	
561520	Tour Operators [10]	$22.0 [10]	
561591	Convention and Visitors Bureaus	$22.0	
561599	All Other Travel Arrangement and Reservation Services	$22.0	
561611	Investigation Services	$22.0	
561612	Security Guards and Patrol Services	$22.0	
561613	Armored Car Services	$22.0	
561621	Security Systems Services (except Locksmiths)	$22.0	
561622	Locksmiths	$22.0	
561710	Exterminating and Pest Control Services	$12.0	
561720	Janitorial Services	$19.5	
561730	Landscaping Services	$8.0	
561740	Carpet and Upholstery Cleaning Services	$6.0	
561790	Other Services to Buildings and Dwellings	$8.0	
561910	Packaging and Labeling Services	$12.0	
561920	Convention and Trade Show Organizers [10]	$12.0 [10]	
561990	All Other Support Services	$12.0	
	Subsector 562—Waste Management and Remediation Services		
562111	Solid Waste Collection	$41.5	
562112	Hazardous Waste Collection	$41.5	
562119	Other Waste Collection	$41.5	
562211	Hazardous Waste Treatment and Disposal	$41.5	
562212	Solid Waste Landfill	$41.5	
562213	Solid Waste Combustors and Incinerators	$41.5	
562219	Other Nonhazardous Waste Treatment and Disposal	$41.5	
562910	Remediation Services	$22.0	
562910 (Exception)	Environmental Remediation Services [14]		750 [14]
562920	Materials Recovery Facilities	$22.0	
562991	Septic Tank and Related Services	$8.0	
562998	All Other Miscellaneous Waste Management Services	$8.0	
	Sector 61—Educational Services **Subsector 611—Educational Services**		
611110	Elementary and Secondary Schools	$12.0	
611210	Junior Colleges	$22.0	
611310	Colleges, Universities and Professional Schools	$30.0	
611410	Business and Secretarial Schools	$8.0	
611420	Computer Training	$12.0	
611430	Professional and Management Development Training	$12.0	
611511	Cosmetology and Barber Schools	$8.0	
611512	Flight Training	$30.0	
611513	Apprenticeship Training	$8.0	
611519	Other Technical and Trade Schools	$16.5	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
611519 (Exception)	Job Corps Centers [16]	$41.5 [16]	
611610	Fine Arts Schools	$8.0	
611620	Sports and Recreation Instruction	$8.0	
611630	Language Schools	$12.0	
611691	Exam Preparation and Tutoring	$8.0	
611692	Automobile Driving Schools	$8.0	
611699	All Other Miscellaneous Schools and Instruction	$12.0	
611710	Educational Support Services	$16.5	
	Sector 62—Health Care and Social Assistance **Subsector 621—Ambulatory Health Care Services**		
621111	Offices of Physicians (except Mental Health Specialists)	$12.0	
621112	Offices of Physicians, Mental Health Specialists	$12.0	
621210	Offices of Dentists	$8.0	
621310	Offices of Chiropractors	$8.0	
621320	Offices of Optometrists	$8.0	
621330	Offices of Mental Health Practitioners (except Physicians)	$8.0	
621340	Offices of Physical, Occupational and Speech Therapists and Audiologists	$8.0	
621391	Offices of Podiatrists	$8.0	
621399	Offices of All Other Miscellaneous Health Practitioners	$8.0	
621410	Family Planning Centers	$12.0	
621420	Outpatient Mental Health and Substance Abuse Centers	$16.5	
621491	HMO Medical Centers	$35.0	
621492	Kidney Dialysis Centers	$41.5	
621493	Freestanding Ambulatory Surgical and Emergency Centers	$16.5	
621498	All Other Outpatient Care Centers	$22.0	
621511	Medical Laboratories	$35.0	
621512	Diagnostic Imaging Centers	$16.5	
621610	Home Health Care Services	$16.5	
621910	Ambulance Services	$16.5	
621991	Blood and Organ Banks	$35.0	
621999	All Other Miscellaneous Ambulatory Health Care Services	$16.5	
	Subsector 622—Hospitals		
622110	General Medical and Surgical Hospitals	$41.5	
622210	Psychiatric and Substance Abuse Hospitals	$41.5	
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	$41.5	
	Subsector 623—Nursing and Residential Care Facilities		
623110	Nursing Care Facilities (Skilled Nursing Facilities)	$30.0	
623210	Residential Intellectual and Developmental Disability Facilities	$16.5	
623220	Residential Mental Health and Substance Abuse Facilities	$16.5	
623311	Continuing Care Retirement Communities	$30.0	
623312	Assisted Living Facilities for the Elderly	$12.0	
623990	Other Residential Care Facilities	$12.0	
	Subsector 624—Social Assistance		
624110	Child and Youth Services	$12.0	
624120	Services for the Elderly and Persons with Disabilities	$12.0	
624190	Other Individual and Family Services	$12.0	
624210	Community Food Services	$12.0	
624221	Temporary Shelters	$12.0	
624229	Other Community Housing Services	$16.5	
624230	Emergency and Other Relief Services	$35.0	
624310	Vocational Rehabilitation Services	$12.0	
624410	Child Day Care Services	$8.0	
	Sector 71—Arts, Entertainment and Recreation **Subsector 711—Performing Arts, Spectator Sports and Related Industries**		
711110	Theater Companies and Dinner Theaters	$22.0	
711120	Dance Companies	$12.0	
711130	Musical Groups and Artists	$12.0	
711190	Other Performing Arts Companies	$30.0	
711211	Sports Teams and Clubs	$41.5	
711212	Racetracks	$41.5	
711219	Other Spectator Sports	$12.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
711310	Promoters of Performing Arts, Sports and Similar Events with Facilities	$35.0	
711320	Promoters of Performing Arts, Sports and Similar Events without Facilities	$16.5	
711410	Agents and Managers for Artists, Athletes, Entertainers and Other Public Figures	$12.0	
711510	Independent Artists, Writers, and Performers	$8.0	
	Subsector 712—Museums, Historical Sites and Similar Institutions		
712110	Museums	$30.0	
712120	Historical Sites	$8.0	
712130	Zoos and Botanical Gardens	$30.0	
712190	Nature Parks and Other Similar Institutions	$8.0	
	Subsector 713—Amusement, Gambling and Recreation Industries		
713110	Amusement and Theme Parks	$41.5	
713120	Amusement Arcades	$8.0	
713210	Casinos (except Casino Hotels)	$30.0	
713290	Other Gambling Industries	$35.0	
713910	Golf Courses and Country Clubs	$16.5	
713920	Skiing Facilities	$30.0	
713930	Marinas	$8.0	
713940	Fitness and Recreational Sports Centers	$8.0	
713950	Bowling Centers	$8.0	
713990	All Other Amusement and Recreation Industries	$8.0	
	Sector 72—Accommodation and Food Services **Subsector 721—Accommodation**		
721110	Hotels (except Casino Hotels) and Motels	$35.0	
721120	Casino Hotels	$35.0	
721191	Bed-and-Breakfast Inns	$8.0	
721199	All Other Traveler Accommodation	$8.0	
721211	RV (Recreational Vehicle) Parks and Campgrounds	$8.0	
721214	Recreational and Vacation Camps (except Campgrounds)	$8.0	
721310	Rooming and Boarding Houses, Dormitories, and Workers' Camps	$8.0	
	Subsector 722—Food Services and Drinking Places		
722310	Food Service Contractors	$41.5	
722320	Caterers	$8.0	
722330	Mobile Food Services	$8.0	
722410	Drinking Places (Alcoholic Beverages)	$8.0	
722511	Full-Service Restaurants	$8.0	
722513	Limited-Service Restaurants	$12.0	
722514	Cafeterias, Grill Buffets, and Buffets	$30.0	
722515	Snack and Nonalcoholic Beverage Bars	$8.0	
	Sector 81—Other Services (Except Public Administration) **Subsector 811—Repair and Maintenance**		
811111	General Automotive Repair	$8.0	
811112	Automotive Exhaust System Repair	$8.0	
811113	Automotive Transmission Repair	$8.0	
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$8.0	
811121	Automotive Body, Paint and Interior Repair and Maintenance	$8.0	
811122	Automotive Glass Replacement Shops	$12.0	
811191	Automotive Oil Change and Lubrication Shops	$8.0	
811192	Car Washes	$8.0	
811198	All Other Automotive Repair and Maintenance	$8.0	
811211	Consumer Electronics Repair and Maintenance	$8.0	
811212	Computer and Office Machine Repair and Maintenance	$30.0	
811213	Communication Equipment Repair and Maintenance	$12.0	
811219	Other Electronic and Precision Equipment Repair and Maintenance	$22.0	
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance.	$8.0	
811411	Home and Garden Equipment Repair and Maintenance	$8.0	
811412	Appliance Repair and Maintenance	$16.5	
811420	Reupholstery and Furniture Repair	$8.0	
811430	Footwear and Leather Goods Repair	$8.0	
811490	Other Personal and Household Goods Repair and Maintenance	$8.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
	Subsector 812—Personal and Laundry Services		
812111	Barber Shops	$8.0	
812112	Beauty Salons	$8.0	
812113	Nail Salons	$8.0	
812191	Diet and Weight Reducing Centers	$22.0	
812199	Other Personal Care Services	$8.0	
812210	Funeral Homes and Funeral Services	$8.0	
812220	Cemeteries and Crematories	$22.0	
812310	Coin-Operated Laundries and Drycleaners	$8.0	
812320	Drycleaning and Laundry Services (except Coin-Operated)	$6.0	
812331	Linen Supply	$35.0	
812332	Industrial Launderers	$41.5	
812910	Pet Care (except Veterinary) Services	$8.0	
812921	Photofinishing Laboratories (except One-Hour)	$22.0	
812922	One-Hour Photofinishing	$16.5	
812930	Parking Lots and Garages	$41.5	
812990	All Other Personal Services	$8.0	
	Subsector 813—Religious, Grantmaking, Civic, Professional and Similar Organizations		
813110	Religious Organizations	$8.0	
813211	Grantmaking Foundations	$35.0	
813212	Voluntary Health Organizations	$30.0	
813219	Other Grantmaking and Giving Services	$41.5	
813311	Human Rights Organizations	$30.0	
813312	Environment, Conservation and Wildlife Organizations	$16.5	
813319	Other Social Advocacy Organizations	$8.0	
813410	Civic and Social Organizations	$8.0	
813910	Business Associations	$8.0	
813920	Professional Organizations	$16.5	
813930	Labor Unions and Similar Labor Organizations	$8.0	
813940	Political Organizations	$8.0	
813990	Other Similar Organizations (except Business, Professional, Labor, and Political Organizations).	$8.0	
*	* * * * * *	*	

Footnotes

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2. *NAICS code 237990*—Dredging: To be considered small for purposes of Government procurement, a firm must perform at least 40 percent of the volume dredged with its own equipment or equipment owned by another small dredging concern.

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8. *NAICS Codes 522110, 522120, 522130, 522190, and 522210*—A financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year. ''Assets'' for the purposes of this size standard means the assets defined according to the Federal Financial Institutions Examination Council 041 call report form for NAICS codes 522110, 522120, 522190, and 522210 and the National Credit Union Administration 5300 call report form for NAICS code 522130.

9. *NAICS codes 531110, 531120, 531130, and 531190*—Leasing of Building Space to the Federal Government by Owners: For Government procurement, a size standard of $41.5 million in gross receipts applies to the owners of building space leased to the Federal Government. The standard does not apply to an agent.

10. *NAICS codes 488510 (part) 531210, 541810, 561510, 561520, and 561920*—As measured by total revenues, but excluding funds received in trust for an unaffiliated third party, such as bookings or sales subject to commissions. The commissions received are included as revenues.

* * * * *

12. *NAICS code 561210*—Facilities Support Services:

(a) If one or more activities of Facilities Support Services as defined in paragraph (b) (below in this footnote) can be identified with a specific industry and that industry accounts for 50 percent or more of the value of an entire procurement, then the proper classification of the procurement is that of the specific industry, not Facilities Support Services.

(b) ''Facilities Support Services'' requires the performance of three or more separate activities in the areas of services or specialty trade contractors industries. If services are performed, these service activities must each be in a separate NAICS industry. If the procurement requires the use of specialty trade contractors (plumbing, painting, plastering, carpentry, etc.), all such specialty trade contractors activities are considered a single activity and classified as ''Building and Property Specialty Trade Services.'' Since ''Building and Property Specialty Trade Services'' is only one activity, two additional activities of separate NAICS industries are required for a procurement to be classified as ''Facilities Support Services.''

13. *NAICS code 238990*—Building and Property Specialty Trade Services: If a procurement requires the use of multiple specialty trade contractors (*i.e.,* plumbing, painting, plastering, carpentry, etc.), and no specialty trade accounts for 50 percent or more of the value of the procurement, all such specialty trade contractors activities are considered a single activity and classified as Building and Property Specialty Trade Services.

14. *NAICS 562910*—Environmental Remediation Services:

(a) For SBA assistance as a small business concern in the industry of Environmental Remediation Services, other than for Government procurement, a concern must be engaged primarily in furnishing a range of services for the remediation of a contaminated environment to an acceptable condition including, but not limited to, preliminary assessment, site inspection, testing, remedial investigation, feasibility studies, remedial design, containment, remedial action, removal of contaminated

materials, storage of contaminated materials and security and site closeouts. If one of such activities accounts for 50 percent or more of a concern's total revenues, employees, or other related factors, the concern's primary industry is that of the particular industry and not the Environmental Remediation Services Industry.

(b) For purposes of classifying a Government procurement as Environmental Remediation Services, the general purpose of the procurement must be to restore or directly support the restoration of a contaminated environment (such as, preliminary assessment, site inspection, testing, remedial investigation, feasibility studies, remedial design, remediation services, containment, removal of contaminated materials, storage of contaminated materials or security and site closeouts), although the general purpose of the procurement need not necessarily include remedial actions. Also, the procurement must be composed of activities in three or more separate industries with separate NAICS codes or, in some instances (*e.g.,* engineering), smaller sub-components of NAICS codes with separate, distinct size standards. These activities may include, but are not limited to, separate activities in industries such as: Heavy Construction; Specialty Trade Contractors; Engineering Services; Architectural Services; Management Consulting Services; Hazardous and Other Waste Collection; Remediation Services, Testing Laboratories; and Research and Development in the Physical, Engineering and Life Sciences. If any activity in the procurement can be identified with a separate NAICS code, or component of a code with a separate distinct size standard, and that industry accounts for 50 percent or more of the value of the entire procurement, then the proper size standard is the one for that particular industry, and not the Environmental Remediation Service size standard.

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16. *NAICS code 611519*—Job Corps Centers. For classifying a Federal procurement, the purpose of the solicitation must be for the management and operation of a U.S. Department of Labor Job Corps Center. The activities involved include admissions activities, life skills training, educational activities, comprehensive career preparation activities, career development activities, career transition activities, as well as the management and support functions and services needed to operate and maintain the facility. For SBA assistance as a small business concern, other than for Federal Government procurements, a concern must be primarily engaged in providing the services to operate and maintain Federal Job Corps Centers.

17. *NAICS code 115310 (Support Activities for Forestry)*—Forest Fire Suppression and Fuels Management Services are two components of Support Activities for Forestry. Forest Fire Suppression includes establishments which provide services to fight forest fires. These firms usually have fire-fighting crews and equipment. Fuels Management Services firms provide services to clear land of hazardous materials that would fuel forest fires. The treatments used by these firms may include prescribed fire, mechanical removal, establishing fuel breaks, thinning, pruning, and piling.

18. *NAICS code 541519*—An Information Technology Value Added Reseller (ITVAR) provides a total solution to information technology acquisitions by providing multi-vendor hardware and software along with significant value added services. Significant value added services consist of, but are not limited to, configuration consulting and design, systems integration, installation of multi-vendor computer equipment, customization of hardware or software, training, product technical support, maintenance, and end user support. For purposes of Government procurement, an information technology procurement classified under this exception and 150-employee size standard must consist of at least 15% and not more than 50% of value added services, as measured by the total contract price. In addition, the offeror must comply with the manufacturing performance requirements, or comply with the non-manufacturer rule by supplying the products of small business concerns, unless SBA has issued a class or contract specific waiver of the non-manufacturer rule. If the contract consists of less than 15% of value added services, then it must be classified under a NAICS manufacturing industry. If the contract consists of more than 50% of value added services, then it must be classified under the NAICS industry that best describes the predominate service of the procurement.

* * * * *

20. *NAICS code 511210*—For purposes of Government procurement, the purchase of software subject to potential waiver of the nonmanufacturer rule pursuant to § 121.1203(d) should be classified under this NAICS code.

■ 3. Amend § 121.502 by revising paragraph (a)(2) to read as follows:

§ 121.502 What size standards are applicable to programs for sales and leases of Government property?

(a) * * *

(2) A concern not primarily engaged in manufacturing is small for sales or leases of Government property if it has annual receipts not exceeding $8 million.

* * * * *

■ 4. Amend § 121.512 by revising paragraph (b) to read as follows:

§ 121.512 What is the size standard for stockpile purchases?

* * * * *

(b) Its annual receipts, together with its affiliates, do not exceed $67.5 million.

Christopher M. Pilkerton,

Acting Administrator.

[FR Doc. 2019–14980 Filed 7–17–19; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No.: FAA–2019–0562; Amdt. No. 91–355]

RIN 2120–AL16

Revision to Automatic Dependent Surveillance-Broadcast (ADS–B) Out Equipment and Use Requirements

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

ACTION: Interim final rule.

SUMMARY: This interim final rule modifies the requirement that all aircraft equipped with Automatic Dependent Surveillance-Broadcast Out (ADS–B Out) must transmit at all times. This rulemaking provides an exception to ADS–B requirements, removing the transmission requirement for sensitive operations conducted by Federal, State and local government entities in matters of national defense, homeland security, intelligence and law enforcement. The changes provide relief to those Federal, State and local government agencies that operate aircraft equipped with ADS–B Out but need the ability to terminate the transmission signal when conducting sensitive national defense, homeland security, intelligence and law enforcement missions that could be compromised by transmitting real time identification and positional flight information over ADS–B. This rulemaking also allows the FAA to except certain aircraft from operating a transponder or transmitting ADS–B Out, when doing so would jeopardize Air Traffic Control (ATC) functions.

DATES: This rule is effective on July 18, 2019.

Comments must be received on or before September 16, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0562 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9

a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT: Scott Rosenbloom, Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–2943; email *scott.rosenbloom@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Authority and Good Cause for This Rulemaking

A. Legal Authority

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103, Sovereignty and use of airspace, and Subpart III, Section 44701, General requirements. Under section 40103, the FAA is charged with prescribing regulations on: (1) The flight of aircraft, including regulations on safe altitudes; (2) the navigation, protection, and identification of aircraft; and (3) the safe and efficient use of the navigable airspace. Under section 44701, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce and national security.

This interim final rule is within the scope of sections 40103 and 44701 because it excepts certain operations from the ADS–B Out and transponder-on requirements in order to preserve the security and safety of these operations, and the safe execution of air traffic control functions.

B. Good Cause for Dispensing With Notice and Comment and for Immediate Adoption

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C.) authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking notice and comment prior to the rulemaking.

The FAA finds there is good cause to issue the rule without seeking prior notice and comment because complying with the transmission requirement while waiting for a proposed rule to be finalized will draw greater attention to operational vulnerabilities that expose government aircraft performing sensitive missions to immediate risk and compromise the operations security of missions necessary for national defense, homeland security, intelligence and law enforcement. In support of this determination, the FAA notes that other organizations have discussed these vulnerabilities and have urged FAA to address them promptly, including in the 2018 GAO Report *Urgent Need for DOD and FAA to Address Risks and Improve Planning for Technology That Tracks Military Aircraft (GAO–18–177),* which can be found in the docket for this interim final rule.

Additionally, the FAA finds good cause to revise the regulation to permit pilots to turn off their transponders in certain circumstances where the safe provision of air traffic control services would be compromised. By regulation, a pilot is required in controlled airspace to operate with his or her transponder on at all times. During the development of this rule, the FAA determined there are circumstances when air traffic control has directed the pilots of non-lead aircraft engaged in formation flights to turn off their transponders. Controllers took this action because the close proximity of the aircraft in formation flight creates a risk to the safe execution of ATC services through audio and visual collision alerts and overlapping information displayed to the controller. As the safe provision of air traffic services necessitates continuation of ATC's policy, seeking prior public notice and comment on this provision is unnecessary.

In addition, in accordance with 5 U.S.C. 553(d)(1), the FAA is making this interim final rule effective upon publication because it is a substantive rule that relieves a restriction and there is an immediate need for operators conducting sensitive government missions to exercise relief from the transmission requirement.

II. Comments Invited

Consistent with the Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 11034; February 26, 1979), which provide that to the maximum extent possible, operating administrations for the DOT should provide an opportunity for public comment on regulations issued without prior notice, the Department requests comment on this interim final rule. The Department encourages persons to participate in this rulemaking by submitting comments. The Department will consider late filed comments to the extent practicable. This interim final rule may be amended based on comments received.

III. Background

On October 7, 2007, the FAA published a notice of proposed rulemaking (NPRM) to mandate ADS–B Out.[1] The FAA deemed it critical to move from ground-based surveillance and navigation to more dynamic and accurate airborne-based systems and procedures in order to modernize America's air transportation system to make flying even safer, more efficient, and more predictable. ADS–B equipment is an advanced surveillance technology that combines an aircraft's positioning source, aircraft avionics, and a ground infrastructure to create an accurate surveillance interface between aircraft and air traffic control.

ADS–B Out, which is the subject of this rulemaking, periodically broadcasts information about each aircraft, such as identification, current position, altitude, and velocity, through an onboard transmitter. ADS–B Out provides air traffic controllers with real-time position information that is, in most cases, more accurate than the information available with current radar-based systems. With more accurate information, ATC will be able to position and separate aircraft with improved precision and timing.

In response to the ADS–B Out NPRM published in 2007, the Department of Defense (DOD) submitted a comment[2] identifying concerns with the mandate

[1] *Automatic Dependent Surveillance—Broadcast (ADS–B) Out Performance Requirements to Support Air Traffic Control (ATC) Service,* NPRM, 72 FR 56947 (Oct. 5, 2007).

[2] *https://www.regulations.gov/docket?D=FAA-2007-29305.*

for all aircraft equipped with ADS–B Out to transmit that information at all times. The concern was based on this new standard being adopted by a multitude of aviation authorities worldwide, advancing aircraft surveillance capabilities, but subjecting it to potential security vulnerabilities. On May 28, 2010, the FAA published the final rule, *Automatic Dependent Surveillance-Broadcast (ADS–B) Out Performance Requirements to Support Air Traffic Control (ATC) Service.*[3] The final rule was effective on August 11, 2010, and mandates that all aircraft operating in the airspace described in § 91.225 of the rule have ADS–B Out technology operational by January 1, 2020. Additionally, the final rule requires aircraft equipped with ADS–B Out technology to transmit at all times, irrespective of the date of equipage. The final rule did not include a national security or law enforcement exception to the requirement that all aircraft that are equipped with ADS–B Out must transmit ADS–B Out at all times, and the FAA noted that it was not operationally feasible to assign different performance requirements dependent on the nature of the operation. However, the FAA did state that it would collaborate with the DoD and other federal agencies to accommodate national defense missions while supporting the needs of all other NAS users.

Over the last few years, the rapid evolution of flight tracking technology in the private sector has impaired the ability of Federal, State and local government entities to successfully execute sensitive missions for the purposes of national defense, homeland security, intelligence and law enforcement when required to transmit ADS–B Out. The FAA has hosted multiple interagency meetings to discuss ADS–B security risk mitigations for sensitive flights. Interagency participants included DOD, Department of Homeland Security (DHS), Federal Bureau of Investigation (FBI), and other intelligence and law enforcement entities. All interagency participants voiced strong concerns about the negative impact to their respective missions from public access to real time ADS–B flight identification and positional data.

Additionally, the FAA is aware of some instances where operating a transponder or transmitting ADS–B Out would jeopardize the safe execution of air traffic control functions. For example, when aircraft are conducting formation flight, the close proximity of the aircraft to each other causes distracting audio and visual alerts on a controller's display. Controllers are able to silence these alerts, but are still subject to multiple, overlapping information elements on the controller's display that make it difficult to discern information.

This rule will give the FAA the necessary flexibility to adjust its air traffic control procedures to accommodate sensitive government missions and otherwise ensure the safe execution of air traffic control functions. The FAA expects this rule to maintain the safety and efficiency of the NAS without negative effect on users.

IV. Discussion of the Rule

This rulemaking amends Title 14, Code of Federal Regulations (CFR), § 91.225(f), to add exceptions to the requirement that each person operating an aircraft equipped with ADS–B Out must operate such equipment in the transmit mode at all times. Section 91.225, paragraph (f), is revised to provide relief from the mandatory transmit requirement for sensitive missions for the purposes of national defense, homeland security, intelligence and law enforcement where transmitting ADS–B Out would compromise safety or the security of the mission. Paragraph (f) is further revised to allow ATC to direct aircraft not to transmit if transmitting would jeopardize the safe execution of air traffic control functions. This rulemaking also amends 14 CFR 91.215(c) to expressly allow ATC to direct aircraft to cease transponder operations in situations where operating the transponder would jeopardize the safe execution of ATC functions.

A. Exception for Aircraft Performing a Sensitive Mission for National Defense, Homeland Security, Intelligence or Law Enforcement Purposes

The FAA acknowledges that there will be some sensitive missions conducted by Federal, State, or local governments that could be compromised by sending flight data over ADS–B. Therefore, this rulemaking allows the aircrew to disable ADS–B transmissions if the aircraft is performing a sensitive mission for the purposes of national defense, homeland security, intelligence or law enforcement *and* if transmitting could reasonably be expected to compromise the security security of the mission or pose a risk to the aircraft, crew, or people and property in the air or on the ground.

Aircraft that transmit in compliance with § 91.225(f) may be detectable by the general public using readily available and inexpensive open source third party networked receivers. ADS–B Out avionics transmit flight data information once per second, including critical information such as the aircraft identification, Global Positioning System position, velocity, and altitude. Independent third party flight tracking software is capable of interpreting the raw ADS–B Out data and presenting a graphical display of the aircraft's exact flight path over the ground in real time.

The proliferation of open source third party flight tracking networks is generally not a concern for non-sensitive flight operations, which comprise the overwhelming majority of total flight operations. Commercial airlines, in particular, have embraced open information sharing of their flight data since the late 1990s. However, if the success of a sensitive flight mission is dependent on its ability to operate undetected by the potential adversary or target, a third party's ability to independently track who and where an aircraft is in real time can pose a risk to the success of the mission, and, at times, to the safety of the personnel and assets conducting the mission.

The operations security of a sensitive government mission is considered compromised when an adversary is able to obtain critical information about that mission because the adversary now has the potential to use that critical information to prevent the successful completion of the mission, including endangering the aircraft. Specifically, special U.S. Federal flights, State or local government flights, including contractual flights in support of those operations, conducting sensitive missions, such as but not limited to, combat air patrol, intercept, counter-drug, counter-terrorism, VIP transport, homeland security, and border surveillance may be relieved from openly broadcasting their identity and position over a link that is easily received and resolved by third-party actors and the general public.

The FAA will defer to each agency regarding whether a mission falls under this exception, and determine whether transmitting would compromise the operations security of the mission or pose a safety risk to the aircraft, crew, or people and property in the air or on the ground. Once the FAA receives a request to terminate broadcasting, the FAA will issue authorizations to turn ADS–B Out off following an assessment that the operations can be accommodated without any negative impact on the safety and efficiency of

[3] *Automatic Dependent Surveillance-Broadcast (ADS–B) Out Performance Requirements to Support Air Traffic Control (ATC) Service,* Final Rule, 75 FR 30193 (May 28, 2010).

the NAS. The FAA will not make an independent assessment of national security, homeland security, or law enforcement considerations. The purpose of the rule is to allow law enforcement and other security agencies to take appropriate measures to protect operational security and the safety of their operators. The FAA expects that each agency will establish its own policies and conduct its own assessment to determine whether the mission should be excepted from the transmitting requirement. Because this relief is being granted to support sensitive security operations, however, the FAA anticipates that non-transmission of ADS–B Out will not be routinely used by agencies that have been granted this relief. The FAA further expects that each agency will conduct this assessment on a broad mission set basis; there is no intent for the FAA to administer ADS–B Out off authorizations on a dynamic, per flight, per mission or per unit basis. The FAA believes there will be no impact to safety or the efficient use of the NAS, and as such per mission authorizations are unnecessary and could result in disruption to sensitive operations that must be conducted with immediacy. However, as with all operations in the NAS, ATC will continue to monitor trends and changes that could impact safety and will modify or amend authorizations to the extent that operations have a negative effect.

Once an agency has determined the broad mission sets that should be excepted from the transmitting requirement using its internal policies and assessment criteria, it must contact the FAA for authorization to conduct these broad mission sets without transmitting. In order to maintain both the security of the qualifying mission sets and the safety of the NAS, the FAA must verify the following: Aircraft equipage and the inclusion of that aircraft into existing FAA support and protection processes for the classified and sensitive unclassified missions conducted in the NAS. This verification is necessary to ensure safe separation when qualifying mission sets are excepted from the transmitting requirement. The FAA does not intend to coordinate ADS–B Out off authorizations on a dynamic, per flight, per mission, or per unit basis. Rather, the FAA expects coordination for ADS–B Out off authorization to be handled at the highest possible agency organization level. For instance, ADS–B Out off authorizations for DoD aircraft should be handled at the DoD agency level, not at an individual service level (*i.e.,* Air Force, Army, Navy), and not at an individual unit level (*i.e.,* 89th Airlift Wing at Joint Base Andrews).

To initiate the process, Federal, State and local government organizations should contact FAA System Operations Security via email at *9-ATOR-HQ-IFOS@faa.gov.* To facilitate timely response, government organizations should ensure that the subject line of the email to *9-ATOR-HQ-IFOS@faa.gov* contains ''ADS–B Authorization under 14 CFR 91.225(f)(1)'', and that the body of the email includes the government organization point-of-contact name and contact information. Once a Federal, State or local government entity receives authorization by following the process listed above, it may conduct those operations for which it received authorization without transmitting. The FAA will make adjustments if there is an impact on air traffic control systems, including ADS–B, or the NAS that makes such changes necessary.

There may be some broad mission sets conducted by Federal, State, or local governments that do not meet their internal assessment determination for national security risk or risk to the aircraft, crew, or people and property in the air or on the ground, but may still require relief from the transmission requirement. In these situations, an agency can still seek relief through the exemption process. As such, the FAA recommends that agencies review exemptions where the FAA has provided relief from current transponder requirements, as these current exemptions will provide valuable guidance regarding how FAA will consider additional requests in a way that does not compromise the safety or efficient operation of the NAS. After review, an agency could then request an amendment to those exemptions and add a request for relief from the applicable ADS–B Out requirements under 14 CFR 91.225. For example, the U.S. Navy and U.S. Air Force have exemptions for transponder off areas. These exemptions could be amended to include ADS–B Out relief, or an agency could petition the FAA to designate new operational training areas exempt from the ADS–B transmitting requirement. If no current exemptions exist, an agency could petition for a new exemption under 14 CFR part 11. As in the case of the other provisions of this rule, FAA does not believe that the use of such exemptions should become routine, and should be limited to areas in which such relief represents and integral mission need of the requestor.

B. Exception To Preserve the Safe Execution of Air Traffic Control Functions

This rulemaking also excepts certain aircraft from operating a transponder or transmitting ADS–B, when such transmissions would compromise the safe execution of air traffic control functions as determined by ATC. The exception allows ATC to direct aircraft not to transmit only when ATC has determined that such transmissions would compromise the safe execution of ATC functions.

One instance during which aircraft operating a transponder or transmitting ADS–B in accordance with § 91.215(c) and § 91.225(f), respectively, causes distracting alerts for air traffic controllers is when all aircraft flying in formation are transmitting. Formation flight involves more than one aircraft which, by prior arrangement between the pilots, operate as a single aircraft with regard to navigation and position reporting to ATC. Separation between aircraft within the formation is the responsibility of the flight lead and the pilots of the other aircraft in the flight. This includes transition periods when aircraft within the formation are maneuvering to attain separation from each other to effect individual control, and during join-up and breakaway. A standard formation is one in which a proximity of no more than 1 mile laterally or longitudinally and within 100 feet vertically from the flight leader is maintained by each wingman.[4] Formation flying is used by both military and civilian pilots.

During formation flight, the close proximity of aircraft and their data/identification tags displayed on the radar display can, at a minimum, clutter the ATC display making it hard for ATC to determine the exact location of the aircraft to provide appropriate separation from other aircraft. Additionally, an air traffic controller will receive repeated audio and visual alerts (flashing data tag) that aircraft are within close proximity to each other. These alerts can distract controllers and redirect their attention to aircraft with approved separation and away from other instances where the controller may need to provide control instruction to maintain necessary separation. In these cases, once aircraft are ''joined up'' as a flight, it is in the best interest of flight safety to direct subsequent ''wingmen'' in the flight to squawk stand-by or stop squawk since control instructions are provided to only the lead and there are established

[4] Aeronautical Information Manual, Pilot/Controller Glossary.

separation minima from formation flights. In the instance of non-standard formation, it is general practice to have the lead aircraft squawk, along with the trail/last aircraft, a subset beacon code with altitude. In order to minimize these conflicting or overlapping data reports, this rule allows ATC to direct only the lead aircraft flying in formation to transmit ADS–B or operate his or her transponder.

The previous example illustrates one instance the FAA has identified where operating a transponder or transmitting ADS–B jeopardizes the safe execution of air traffic control functions. This requirement should not be construed as requiring that all aircraft equip such that the pilot can turn ADS–B transmission off. Rather, this requirement provides ATC with the flexibility to direct pilots to turn ADS–B or transponder equipment off in certain situations. If a pilot is directed to turn ADS–B off, and is unable to do so, ATC will work with the pilot to determine a safe alternative course of action. Ultimately, this rule allows a controller to direct pilots to turn off ADS–B or transponder equipment if ATC determines that leaving the equipment on would jeopardize the safe execution of air traffic control functions. The FAA expects operators to continue using the exemption process for operations that do not meet the safe execution of air traffic control functions standard included in this rule.

V. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39), as amended, 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995).

In conducting these analyses, the FAA has determined that this interim final rule has benefits that justify its costs. This rule is a significant regulatory action, as defined in section 3(f) of Executive Order 12866, as it raises novel policy issues contemplated under that Executive Order. As notice and comment under 5 U.S.C. 553 are not required for this interim final rule, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 regarding impacts on small entities are not required. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the threshold identified previously.

A. Regulatory Evaluation

Prior to initiating this interim final rule, the FAA considered three alternatives, all of which were deemed inadequate because they failed to meet sensitive U.S. Government operations security needs, were deemed untimely with regard to implementation prior to January 1, 2020, or may result in higher costs than this rule.

The first alternative to this rule that was considered was masking the identity of a sensitive aircraft while still transmitting ADS–B Out. In this scenario, third parties would still be able to receive ADS–B Out data on the aircraft's precise location/track, velocity, and altitude. DoD aircraft routinely enter and exit Special Use Airspace, so third parties can reasonably assume that ADS–B tracks entering and exiting Special Use Airspace are associated with DoD aircraft, thus rendering the masked identity ineffective. Likewise, low altitude surveillance conducted by Federal agencies or state/local law enforcement agencies has a distinctive track/flight pattern that also renders the masked identity ineffective. In addition, FAA held a face-to-face meeting with interagency participants on June 30, 2017, and asked interagency participants whether masking would be a sufficient alternative to address their operations security concerns (OPSEC). Interagency representatives unanimously stated that masking was insufficient; their preferred solution to mitigate operational security issues was authority to turn ADS–B Out off.

The second alternative considered by the FAA was encryption of the ADS–B Out transmissions for sensitive aircraft; however, no encryption solution currently exists. The FAA will monitor technological advances and consider using future technological solutions that could be feasible alternatives, including encryption.

The third alternative considered by the FAA is the use of the exemption process for agencies to petition the FAA for authority to turn ADS–B Out off. For this alternative, the technical solution is the same as the technical solution for this rule; however it is less efficient. The exemption process would require review by multiple FAA offices, instead of review by the one FAA office designated by this rule. Review by multiple FAA offices and the requirement to publish certain information for each exemption in the **Federal Register** would increase overall FAA processing time for each request. Finally, the exemption process requires agencies to submit their requests to the FAA at least 120 days in advance of the date they need the exemption to be in place.

This interim final rule allows the FAA to except certain aircraft from operating a transponder or transmitting ADS–B Out, when doing so would compromise certain sensitive government missions or jeopardize the safe execution of ATC functions. In both scenarios, the aircraft will continue to rely on existing equipment to transmit with ATC thereby maintaining safety of flight operations.

In the first instance, to preserve the safety and security of certain sensitive government missions, this rule excepts aircraft performing missions for the purposes of national defense, homeland security, intelligence or law enforcement from transmitting ADS–B Out if transmitting out could reasonably be expected to compromise the mission or pose a risk to the aircraft, crew, or people and property on the ground. The FAA recognizes that the lack of encryption over the ADS–B Out data link could compromise certain missions or put aircrew, aircraft and personnel and property on the ground at risk. As previously stated in this preamble, those agencies performing safety and security sensitive missions will notify the FAA one-time at the highest possible agency organizational level as opposed to on a dynamic, per mission, per flight or per unit basis to exclude them from the requirement.

In the second instance, this rule excepts certain aircraft from operating a transponder or transmitting ADS–B Out when transmitting would compromise

the safe execution of air traffic services. At this time, the only operation of which the FAA is aware that would jeopardize the safe execution of air traffic control functions due to operating a transponder or transmitting ADS–B Out requirements is formation flight. Specifically, formation flight causes unnecessary and distracting alerts on ATC displays when all aircraft performing the flight are transmitting out. This rule allows the FAA to except certain aircraft from operating a transponder or transmitting ADS–B Out when doing so would jeopardize ATC functions.

The FAA expects this interim final rule will have benefits that justify its costs since it maintains the safety and security of certain sensitive government missions and allows the FAA to except certain aircraft from operating a transponder or transmitting ADS–B Out when doing so would jeopardize ATC functions. In addition, affected aircraft will continue to rely on existing equipment to transmit with ATC thereby maintaining safety of flight operations.

As stated above, the FAA does not expect this authority to be routinely used by agencies that have been granted this relief. As such, the FAA does not believe that this process will induce a significantly greater volume of flights receiving permission to operate without ADS–B Out broadcasting and will not reduce the general advantages conveyed by ADS–B Out deployment in the U.S. airspace in terms of cost savings and traffic management efficiency.

The FAA also considered potential costs to the public. The FAA does not believe permitting certain categories of missions from operating without ADS–B Out broadcasting will reduce any of the benefits identified in earlier ADS–B Out rulemakings related to other users of the NAS, including safety and efficiency gains through improved situational awareness to pilots voluntarily operating with ADS–B In. In addition, the FAA does not foresee that the authorizations will negatively impact unmanned aircraft system (UAS) integration efforts.

This rule will provide unquantified cost savings by relieving affected operators from applying for exemptions. In the absence of this rule, operators seeking to be excepted from the requirement to operate a transponder or transmit ADS–B Out would have to seek an exemption from the FAA in the future. The cost savings associated with avoiding applying for exemptions will accrue to both the FAA and the agencies seeking exemptions. The FAA does not currently maintain data on the number or type of flights receiving ADS–B Out broadcasting exemptions through the existing exemption process, nor on the length of time it takes agencies to request and receive an exemption and thus is unable to quantify the value of any potential time savings.

B. Regulatory Flexibility Determination

Section 603 of the Regulatory Flexibility Act (RFA) requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever an agency is required by 5 U.S.C. 553 to publish a general notice of proposed rulemaking for any proposed rule. Similarly, section 604 of the RFA requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after being required to publish a general notice of proposed rulemaking. RFA analysis requirements are limited to rulemakings for which the agency ''is required by section 553 or any other law, to publish a general notice of proposed rulemaking for any proposed rule.'' 5 U.S.C. 603(a). FAA found good cause for implementing an immediate effective date. As prior notice and comment under 5 U.S.C. 553 are not required to be provided in this situation, the analyses in 5 U.S.C. 603 and 604 are not required.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this interim final rule and determined that it will respond to a domestic safety objective and is not considered an unnecessary obstacle to trade.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This interim final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

The FAA has determined that there would be no new information collection associated with the revision to § 91.225, paragraph (f), to exempt certain ADS–B Out-equipped entities from the requirement to transmit at all times.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these modified regulations.

However, the FAA has recently learned that in 2018 the European Aviation Safety Agency (EASA) has proposed changes to their ADS–B requirements to accommodate the operations security needs of State aircraft. The EASA final report proposes the following major change to amend the existing implementing rule, (EU) 1206/2011 ACID IR:

Add to point 3 of ANNEX II

(d) State aircraft engaged on nationally sensitive operations or training, that require security and confidentiality.

This change would provide the opportunity for State aircraft operators to revert back to Secondary Surveillance Radar (SSR) for such categories of flights in order to prevent their flight data

information from becoming publicly available on internet platforms. The EASA change for State aircraft is the same technical solution chosen by the FAA for sensitive U.S. Government operators in this rule.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this interim final rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this interim final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, International Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

D. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This interim final rule is expected to be an E.O. 13771 deregulatory action. Details on the deregulatory effects of this rule can be found in the Regulatory Evaluation section. This rule will provide unquantified cost savings by relieving affected operators from applying for exemptions. In the absence of this interim final rule, operators seeking to be excepted from the requirement to operate a transponder or transmit ADS–B Out would have to seek an exemption from the FAA. The cost savings associated with avoiding applying for exemptions will accrue to both the FAA and the operators seeking exemptions. The FAA requests comment on this designation of the rule for E.O. 13771 purposes.

VII. Additional Information

A. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies* or

3. Accessing the Government Publishing Office's web page at *https://govinfo.gov.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677.

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the Federal eRulemaking Portal referenced in item (1) above.

B. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation Safety.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 1155, 20101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–56507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.215 by revising paragraph (c) to read as follows:

§ 91.215 ATC transponder and altitude reporting equipment and use.

* * * * *

(c) *Transponder-on operation.* While in the airspace as specified in paragraph (b) of this section or in all controlled airspace, each person operating an aircraft equipped with an operable ATC transponder maintained in accordance with § 91.413 of this part shall operate the transponder, including Mode C equipment if installed, and shall reply on the appropriate code or as assigned by ATC, unless otherwise directed by ATC when transmitting would jeopardize the safe execution of air traffic control functions.

* * * * *

■ 3. Amend § 91.225 by revising paragraph (f) to read as follows:

§ 91.225 Automatic Dependent Surveillance-Broadcast (ADS–B) Out equipment and use.

* * * * *

(f) Each person operating an aircraft equipped with ADS–B Out must operate this equipment in the transmit mode at all times unless—

(1) Otherwise authorized by the FAA when the aircraft is performing a sensitive government mission for national defense, homeland security, intelligence or law enforcement purposes and transmitting would compromise the operations security of the mission or pose a safety risk to the aircraft, crew, or people and property in the air or on the ground; or

(2) Otherwise directed by ATC when transmitting would jeopardize the safe execution of air traffic control functions.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 106(g), 40103, and 44701(a), in Washington, DC, on July 11, 2019.

Daniel K. Elwell,

Acting Administrator.

[FR Doc. 2019–15248 Filed 7–17–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31261; Amdt. No. 3860]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 18, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 18, 2019.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29 Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary.

This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally

current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866;(2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979) ; and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC on June 28, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, (14 CFR part 97), is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
15-Aug-19	NE	Pender	Pender Muni	9/0817	6/25/19	RNAV (GPS) RWY 15, Orig-B.
15-Aug-19	NE	Pender	Pender Muni	9/0818	6/25/19	RNAV (GPS) RWY 33, Orig-B.
15-Aug-19	ND	Linton	Linton Muni	9/0821	6/25/19	RNAV (GPS) RWY 27, Orig-B.
15-Aug-19	ND	Casselton	Casselton Robert Miller Rgnl	9/0824	6/25/19	RNAV (GPS) RWY 13, Amdt 1A.
15-Aug-19	DE	Middletown	Summit	9/0825	6/26/19	RNAV (GPS) RWY 17, Amdt 2B.
15-Aug-19	DE	Middletown	Summit	9/0826	6/26/19	RNAV (GPS) RWY 35, Amdt 1B.
15-Aug-19	ND	Harvey	Harvey Muni	9/0827	6/25/19	RNAV (GPS) RWY 11, Orig-A.
15-Aug-19	NC	Shelby	Shelby-Cleveland County Rgnl	9/0828	6/25/19	RNAV (GPS) RWY 23, Orig-A.
15-Aug-19	NC	Shelby	Shelby-Cleveland County Rgnl	9/0829	6/25/19	RNAV (GPS) RWY 5, Amdt 2A.
15-Aug-19	NC	Edenton	Northeastern Rgnl	9/0840	6/26/19	RNAV (GPS) RWY 1, Amdt 1.
15-Aug-19	NC	Whiteville	Columbus County Muni	9/0849	6/26/19	RNAV (GPS) RWY 6, Amdt 1.
15-Aug-19	NC	Gastonia	Gastonia Muni	9/0851	6/26/19	RNAV (GPS) RWY 3, Amdt 1A.
15-Aug-19	NC	Gastonia	Gastonia Muni	9/0852	6/26/19	RNAV (GPS) RWY 21, Orig-A.
15-Aug-19	NC	Wadesboro	Anson County—Jeff Cloud Field	9/0889	6/26/19	ILS OR LOC RWY 34, Orig-B.
15-Aug-19	NC	Wadesboro	Anson County—Jeff Cloud Field	9/0891	6/26/19	RNAV (GPS) RWY 16, Amdt 1A.
15-Aug-19	NC	Liberty	Causey	9/0898	6/26/19	RNAV (GPS) RWY 2, Orig-A.
15-Aug-19	NC	Liberty	Causey	9/0900	6/26/19	RNAV (GPS) RWY 20, Orig-A.
15-Aug-19	MT	Laurel	Laurel Muni	9/0914	6/26/19	RNAV (GPS) RWY 22, Amdt 1C.
15-Aug-19	MT	Laurel	Laurel Muni	9/0915	6/26/19	RNAV (GPS) RWY 4, Amdt 1C.
15-Aug-19	NC	Kenansville	Duplin Co	9/0927	6/26/19	RNAV (GPS) RWY 5, Amdt 1.
15-Aug-19	NC	Kenansville	Duplin Co	9/0928	6/26/19	RNAV (GPS) RWY 23, Amdt 1.
15-Aug-19	MT	Circle	Circle Town County	9/0929	6/26/19	RNAV (GPS) RWY 30, Orig-C.
15-Aug-19	MS	Booneville/Baldwyn	Booneville/Baldwyn	9/0945	6/26/19	RNAV (GPS) RWY 15, Amdt 1A.
15-Aug-19	MS	Booneville/Baldwyn	Booneville/Baldwyn	9/0946	6/26/19	RNAV (GPS) RWY 33, Amdt 1A.
15-Aug-19	NV	Winnemucca	Winnemucca Muni	9/0995	6/25/19	RNAV (GPS) RWY 14, Orig.
15-Aug-19	NV	Winnemucca	Winnemucca Muni	9/0997	6/25/19	RNAV (GPS) RWY 32, Orig-A.
15-Aug-19	NV	Tonopah	Tonopah	9/0999	6/25/19	RNAV (GPS) RWY 15, Orig-A.
15-Aug-19	NV	Reno	Reno/Tahoe Intl	9/1000	6/25/19	RNAV (GPS) X RWY 16R, Amdt 1D.
15-Aug-19	MI	Marlette	Marlette Township	9/1024	6/25/19	Takeoff Minimums and Obstacle DP, Orig-A.
15-Aug-19	WA	Spokane	Spokane Intl	9/1063	6/26/19	RNAV (GPS) Y RWY 3, Amdt 2E.
15-Aug-19	WA	Spokane	Spokane Intl	9/1064	6/26/19	RNAV (GPS) Y RWY 8, Amdt 2D.
15-Aug-19	NY	New York	New York Stewart Intl	9/1434	6/26/19	ILS OR LOC RWY 9, ILS RWY 9 (SA CAT I), ILS RWY 9 (CAT II), ILS RWY 9 (CAT III), Amdt 13C.
15-Aug-19	NY	New York	New York Stewart Intl	9/1491	6/26/19	RNAV (GPS) RWY 9, Amdt 1D.
15-Aug-19	NY	New York	New York Stewart Intl	9/1493	6/26/19	RNAV (GPS) RWY 16, Amdt 1C.
15-Aug-19	NY	New York	New York Stewart Intl	9/1497	6/26/19	ILS OR LOC RWY 27, Amdt 1C.
15-Aug-19	LA	New Iberia	Acadiana Rgnl	9/2038	6/18/19	RNAV (GPS) RWY 35, Amdt 1.
15-Aug-19	LA	New Iberia	Acadiana Rgnl	9/2040	6/18/19	RNAV (GPS) RWY 17, Amdt 1A.
15-Aug-19	NY	New York	New York Stewart Intl	9/2466	6/26/19	RNAV (GPS) RWY 27, Amdt 1C.
15-Aug-19	AS	Pago Pago	Pago Pago Intl	9/2558	6/18/19	RNAV (GPS) RWY 5, Orig-A.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3398	6/18/19	VOR/DME OR TACAN RWY 7, Amdt 11C.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3402	6/18/19	ILS OR LOC RWY 25, Amdt 21F.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3403	6/18/19	NDB RWY 25, Amdt 24E.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3404	6/18/19	ILS OR LOC RWY 7, Orig-D.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3406	6/18/19	RNAV (GPS) RWY 25, Amdt 1.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3407	6/18/19	RNAV (GPS) RWY 7, Amdt 1.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3409	6/18/19	RNAV (GPS) RWY 1, Amdt 2.
15-Aug-19	AR	Fort Smith	Fort Smith Rgnl	9/3410	6/18/19	VOR OR TACAN RWY 25, Amdt 20H.
15-Aug-19	AK	Hooper Bay	Hooper Bay	9/4968	6/18/19	VOR/DME RWY 31, Orig-C.
15-Aug-19	HI	Kamuela	Waimea-Kohala	9/6811	6/18/19	VOR/DME RWY 4, Amdt 1A.
15-Aug-19	HI	Kamuela	Waimea-Kohala	9/6812	6/18/19	RNAV (GPS) RWY 22, Orig-B.
15-Aug-19	NH	Lebanon	Lebanon Muni	9/6989	6/18/19	RNAV (GPS) RWY 25, Orig-C.
15-Aug-19	MI	Marlette	Marlette	9/7079	6/18/19	RNAV (GPS) RWY 19, Orig-B.
15-Aug-19	MI	Marlette	Marlette	9/7080	6/18/19	RNAV (GPS) RWY 27, Amdt 1B.
15-Aug-19	MI	Marlette	Marlette	9/7081	6/18/19	RNAV (GPS) RWY 9, Amdt 1B.
15-Aug-19	AK	Golovin	Golovin	9/7802	6/18/19	RNAV (GPS) RWY 3, Amdt 1.
15-Aug-19	SD	Clark	Clark County	9/7853	6/18/19	RNAV (GPS) RWY 13, Orig.
15-Aug-19	AR	Jonesboro	Jonesboro Muni	9/8773	6/18/19	RNAV (GPS) RWY 31, Amdt 1A.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
15-Aug-19	AR	Jonesboro	Jonesboro Muni	9/8774	6/18/19	VOR RWY 23, Amdt 11A.
15-Aug-19	AR	Jonesboro	Jonesboro Muni	9/8783	6/18/19	RNAV (GPS) RWY 5, Amdt 1A.
15-Aug-19	AR	Jonesboro	Jonesboro Muni	9/8792	6/18/19	ILS OR LOC RWY 23, Amdt 2A.
15-Aug-19	NY	New York	New York Stewart Intl	9/8972	6/26/19	RNAV (GPS) RWY 34, Amdt 1C.
15-Aug-19	NY	New York	New York Stewart Intl	9/9030	6/26/19	Takeoff Minimums and Obstacle DP, Amdt 6A.
15-Aug-19	AK	Kodiak	Kodiak	9/9281	6/18/19	ILS Y OR LOC Y RWY 26, Amdt 3B.
15-Aug-19	MQ	Midway Atoll	Henderson Field	9/9335	6/18/19	NDB RWY 24, Orig-B.
15-Aug-19	MQ	Midway Atoll	Henderson Field	9/9340	6/18/19	NDB RWY 6, Orig-B.
15-Aug-19	MQ	Midway Atoll	Henderson Field	9/9341	6/18/19	RNAV (GPS) RWY 6, Orig-C.
15-Aug-19	MQ	Midway Atoll	Henderson Field	9/9342	6/18/19	RNAV (GPS) RWY 24, Orig-C.
15-Aug-19	AL	Clayton	Clayton Muni	9/9348	6/21/19	RNAV (GPS) RWY 27, Amdt 1B.
15-Aug-19	AL	Clayton	Clayton Muni	9/9349	6/21/19	RNAV (GPS) RWY 9, Orig-B.
15-Aug-19	AZ	Prescott	Ernest A Love Field	9/9469	6/26/19	VOR RWY 12, Amdt 2B.
15-Aug-19	OK	Pauls Valley	Pauls Valley Muni	9/9548	6/18/19	RNAV (GPS) RWY 17, Orig-A.
15-Aug-19	NJ	Millville	Millville Muni	9/9944	6/25/19	ILS OR LOC RWY 10, Amdt 2C.
15-Aug-19	MT	Missoula	Missoula Intl	9/9945	6/26/19	ILS Z RWY 12, Amdt 12D.

[FR Doc. 2019–15125 Filed 7–17–19; 8:45 a.m.]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31260; Amdt. No. 3859]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective July 18, 2019. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 18, 2019.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal.

Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97:

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC on June 28, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 15 August 2019

Soldotna, AK, Soldotna, VOR–A, Amdt 8
Hot Springs, AR, Memorial Field, ILS OR LOC RWY 5, Amdt 16
Hot Springs, AR, Memorial Field, RNAV (GPS) RWY 5, Amdt 2
Hot Springs, AR, Memorial Field, Takeoff Minimums and Obstacle DP, Amdt 7
Hot Springs, AR, Memorial Field, VOR RWY 5, Amdt 5
Madera, CA, Madera Muni, RNAV (GPS) RWY 12, Amdt 2
Madera, CA, Madera Muni, RNAV (GPS) RWY 30, Amdt 2
Madera, CA, Madera Muni, Takeoff Minimums and Obstacle DP, Amdt 5
Madera, CA, Madera Muni, VOR RWY 30, Amdt 10, CANCELLED
South Lake Tahoe, CA, Lake Tahoe, LDA RWY 18, Amdt 8
South Lake Tahoe, CA, Lake Tahoe, RNAV (GPS) RWY 18, Amdt 1
Visalia, CA, Visalia Muni, ILS OR LOC RWY 30, Amdt 8
Visalia, CA, Visalia Muni, RNAV (GPS) RWY 12, Amdt 2
Visalia, CA, Visalia Muni, RNAV (GPS) RWY 30, Amdt 2
Visalia, CA, Visalia Muni, Takeoff Minimums and Obstacle DP, Amdt 4
Visalia, CA, Visalia Muni, VOR RWY 12, Amdt 7
Brooksville, FL, Brooksville-Tampa Bay Rgnl, ILS OR LOC RWY 9, Amdt 3
Mount Carmel, IL, Mount Carmel Muni, RNAV (GPS) RWY 4, Orig–B
Mount Carmel, IL, Mount Carmel Muni, RNAV (GPS) RWY 22, Orig–A
Johnson, KS, Stanton County Muni, RNAV (GPS) RWY 17, Amdt 2
Johnson, KS, Stanton County Muni, RNAV (GPS) RWY 35, Amdt 2
Austin, MN, Austin Muni, RNAV (GPS) RWY 17, Amdt 2
Austin, MN, Austin Muni, RNAV (GPS) RWY 35, Amdt 2
Bemidji, MN, Bemidji Rgnl, ILS OR LOC RWY 31, Amdt 6A

[FR Doc. 2019–15126 Filed 7–17–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–495]

Schedules of Controlled Substances: Temporary Placement of *N*-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-Chloro-α-PVP in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration (DEA) is issuing this temporary scheduling order to schedule the synthetic cathinones, *N*-ethylhexedrone (2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; *alpha*-pyrrolidinohexiophenone; trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (2-(ethylamino)-1-(4-methylphenyl)pentan-1-one; trivial name: 4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one; 4′-methyl-*alpha*-pyrrolidinohexanophenone; trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one; trivial name: PV8); and 4′-chloro-*alpha*-pyrrolidinovalerophenone (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one; 4′-chloro-*alpha*-pyrrolidinopentiophenone; trivial name: 4-chloro-α-PVP), and their optical, positional, and geometric isomers, salts, and salts of isomers in schedule I. This action is based on a finding by the Acting Administrator that the placement of these synthetic cathinones in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, possess, import, export, research, or conduct instructional activities or chemical analysis), or propose to handle, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP.

DATES: This temporary scheduling order is effective July 18, 2019, until July 18, 2021. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling [1] for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place *N*-ethylhexedrone; *alpha*-pyrrolidinohexanophenone (α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (MPHP); *alpha*-pyrrolidinoheptaphenone (PV8); and 4-chloro-*alpha*-pyrrolidinovalerophenone (4-chloro-α-PVP) in schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter dated March 9, 2018. The Assistant Secretary responded to this notice of intent by letter dated March 27, 2018, and advised that based on a review by the Food and Drug Administration (FDA), there were currently no approved new drug applications or active investigational new drug applications for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP. The Assistant Secretary also stated that the HHS had no objection to the temporary placement of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I of the CSA.

The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). *N*-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of *N*-ethylhexedrone (2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; *alpha*-pyrrolidinohexiophenone; trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (2-(ethylamino)-1-(4-methylphenyl)pentan-1-one; trivial name: 4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one; 4′-methyl-*alpha*-pyrrolidinohexanophenone; trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one; trivial name: PV8); and 4′-chloro-*alpha*-pyrrolidinovalerophenone (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one; 4′-chloro-*alpha*-pyrrolidinopentiophenone; trivial name: 4-chloro-α-PVP) in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent to temporarily schedule *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in the **Federal Register** on May 1, 2019 (84 FR 18423). That notice of intent identified the six substances using the common names; however, in the three-factor analysis, which DEA made available on *www.regulations.gov* contemporaneously with the publication of the notice of intent, these same substances were identified using the International Union of Pure and Applied Chemistry (IUPAC) nomenclature. This temporary scheduling order provides the common names, as well as the IUPAC names, for all six substances.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP, summarized below, indicate that these synthetic cathinones have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's March 27, 2018 letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov.*

Synthetic Cathinones

Novel synthetic cathinones that mimic the biological effects of substances with stimulant-like effects continue to emerge in the illicit drug market. These novel cathinones, also known as designer drugs, are structurally similar to several drugs of abuse such as schedule I synthetic cathinones (*e.g.,* methcathinone, mephedrone, methylone, pentylone, and 3,4-methylenedioxypyrovalerone (MDPV)). The illicit use of synthetic cathinones has continued throughout the United States, resulting in severe adverse effects, overdoses, and deaths. Indeed, hospital reports, scientific

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

publications, and/or law enforcement reports demonstrate that these types of substances are being abused for their psychoactive properties and they cause harm (*see* DEA 3-Factor Analysis). Recreational effects reported by abusers of synthetic cathinones include: Euphoria, sense of well-being, increased sociability, energy, empathy, increased alertness, improved concentration and focus. Adverse effects such as tachycardia, hypertension, rhabdomyolysis, hyponatremia, seizures, and altered mental status (paranoia, hallucinations, and delusions) have also been reported from the abuse of synthetic cathinones. Consequently, there are documented reports of emergency room admissions and deaths associated with the abuse of synthetic cathinone substances. With several generations of synthetic cathinones having been encountered since 2009, the abuse of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP is impacting or will negatively impact communities.

Law enforcement data indicate that *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP have appeared in the United States' illicit drug market (*see* DEA 3-Factor Analysis). Law enforcement encounters include those reported to the National Forensic Laboratory Information System (NFLIS), a DEA sponsored program that systematically collects drug identification results and associated information from drug cases analyzed by Federal, State, and local forensic laboratories. From January 2012 to September 24, 2018, NFLIS registered 1,131 drug exhibits pertaining to the trafficking, distribution and abuse of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP. These exhibits had a net weight of approximately 18.7 kilograms [3] and were encountered in powder, crystal, rock, resin, capsule and tablet forms.

As observed by the DEA and by the United States Customs and Border Protection (CBP), synthetic cathinones originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. There have been encounters of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP by the CBP (*see* DEA 3-Factor Analysis).

N-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP have no accepted medical use in the United States. *N*-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP have been seized by law enforcement in the United States. The misuse of α-PHP, 4–MEAP, MPHP, and PV8 has been reported to result in adverse effects in humans in the United States. Although no overdose information is currently available for *N*-ethylhexedrone and 4-chloro-α-PVP, law enforcement seizures of these two substances and their pharmacological similarity to currently controlled schedule I synthetic cathinones (*e.g.,* methcathinone, mephedrone, methylone, pentylone, MDPV) suggest that these two synthetic cathinones are likely to produce adverse effects similar to those produced by other synthetic cathinones.

N-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are synthetic cathinones that have pharmacological effects similar to schedule I synthetic cathinone substances such as methcathinone, mephedrone, methylone, pentylone, and MDPV and schedule II stimulants such as methamphetamine and cocaine. The misuse of α-PHP, 4–MEAP, MPHP, and PV8 has been associated with one or more overdoses with some requiring emergency medical intervention in the United States. With no approved medical use and limited safety or toxicological information, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP have emerged on the designer drug market, and the abuse or trafficking of these substances for their psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

N-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are synthetic cathinones that have been identified in the United States' illicit drug market. Evidence indicates that these substances are being substituted for schedule I synthetic cathinones. Products containing synthetic cathinones have been falsely marketed as ''research chemicals,'' ''jewelry cleaner,'' ''stain remover,'' ''plant food or fertilizer,'' ''insect repellants,'' or ''bath salts.'' They have been sold at smoke shops, head shops, convenience stores, adult bookstores, and gas stations. They can also be purchased on the internet. These substances are commonly encountered in the form of powders, crystals, tablets, and capsules. Other encountered forms include resin, rock, liquid, and deposits on plant matter. Law enforcement has encountered *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in powder, crystal, resin, rock, capsule, or tablet forms. The packages of these commercial products usually contain the warning ''not for human consumption,'' most likely in an effort to circumvent statutory restrictions for these substances.

N-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are likely to be abused in the same manner as schedule I synthetic cathinones such as methcathinone, mephedrone, methylone, pentylone, and MDPV. Information from published scientific studies indicate that the most common routes of administration for synthetic cathinones are nasal insufflation by snorting the powder and ingestion by swallowing capsules or tablets. The powder can also be injected or swallowed. Other methods of intake include rectal administration, ingestion by ''bombing'' (wrapping a dose of powder in a paper wrap and swallowing) and intramuscular injection.

Based upon the information collected from case reports, medical journals, and scientific publications including survey data, the main users of synthetic cathinones are youths and young adults. Given that *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are newly emerging synthetic cathinones, it is likely that these substances will be used by the same population. This is consistent with data collected from the use of schedule I synthetic cathinones (*e.g.,* mephedrone, methylone, pentylone, MDPV). According to Monitoring the Future (MTF) survey data,[4] the 2017 annual prevalence rate of synthetic cathinone use was 0.6% for high school seniors and 0.3% for young adults (19—30 years). However, there was an 18 percentage point increase in the perceived risk of trying ''bath salts'' in young adults (aged 19—26 years).

N-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are likely to have duration of effects similar to those of schedule I synthetic cathinones because of their structural and pharmacological similarities. Users report (drug surveys, scientific and medical literature, *etc.*) that the effects of synthetic cathinones occur a few

[3] Not all exhibits had weights recorded in the NFLIS database.

[4] Monitoring the Future (MTF) is a research program conducted at the University of Michigan's Institute for Social Research under grants from NIDA. MTF tracks drug use trends among United States adolescents in the 8th, 10th, and 12th grades and high school graduates into adulthood by conducting national surveys.

minutes to 15 minutes after administration, depending on the synthetic cathinone and the route of administration (oral, insufflation, intravenous, *etc.*), and can last up to three hours.

Evidence indicated that *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are ingested with other substances. This is likely to either heighten the effects or ameliorate the come-down effects of the synthetic cathinones. Co-ingestions can be from the ingestion of multiple products separately or a single product that is composed of multiple substances (*e.g.,* one tablet containing *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, 4-chloro-α-PVP, and other illicit substances). Indeed, law enforcement routinely encounters synthetic cathinone mixtures. Substances found in combination with *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, or 4-chloro-α-PVP are: Other synthetic cathinones (*e.g.,* MDPV, 4-chloromethcathinone, *N*-ethylpentylone, α-PVP), common cutting agents (*e.g.,* caffeine), or other substances of abuse (*e.g.,* methamphetamine, fentanyl, fentanyl analogues, carfentanil, benzodiazepines (*e.g.,* alprazolam), heroin, cocaine, synthetic cannabinoids, fluoroamphetamine, MDMA). Multiple drug use and potential co-ingestions are confirmed by forensic analysis of seized and purchased synthetic cathinone products.

Factor 5. Scope, Duration and Significance of Abuse

Since 2009, the popularity of synthetic cathinones and their associated products has continued, as evidenced by law enforcement seizures, public health information, and media reports. As one synthetic cathinone is controlled, another unscheduled synthetic cathinone appears in the recreational drug market. *N*-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are synthetic cathinones that have been identified in the United States' illicit drug market (*see* DEA 3-Factor Analysis for a full discussion).

Law enforcement data indicate that *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are being abused in the United States as recreational drugs. While law enforcement data are not direct evidence of abuse, the data can infer that a drug has been diverted and abused.[5] Forensic laboratories have confirmed the presence of these substances in drug exhibits received from state, local, and federal law enforcement agencies. From January 2012 to September 24, 2018, there were 1,131 exhibits reported to NFLIS databases (Federal, State and local forensic laboratories) pertaining to the trafficking, distribution and abuse of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP. These exhibits had a net weight of approximately 18.7 kilograms.[6] These data also indicated that the abuse of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP is widespread and has been encountered in many states since 2012 in the United States.

The following information details data obtained from the NFLIS database (queried on September 24, 2018), including dates of first encounter, exhibits/reports, and locations.

N-Ethylhexedrone: NFLIS—233 reports, first encountered in August 2016, locations include: Arizona, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and Wyoming.

α-*PHP:* NFLIS—395 reports, first encountered in May 2014, locations include: Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New Jersey, New York, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.

4–MEAP: NFLIS—105 reports, first encountered in August 2013, locations include: Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Kansas, Louisiana, Maryland, Minnesota, New Hampshire, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, and Texas.

MPHP: NFLIS—71 reports, first encountered in June 2012, locations include: California, Connecticut, Florida, Georgia, Indiana, Kansas, Kentucky, Maine, Minnesota, Missouri, Nebraska, Nevada, New Jersey, Ohio, Pennsylvania, and Texas.

PV8: NFLIS—166 reports, first encountered in December 2013, locations include: Arizona, Connecticut, District of Columbia, Florida, Georgia, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and Wisconsin.

4-Chloro-α-PVP: NFLIS—160 reports, first encountered in December 2015, locations include: California, District of Columbia, Louisiana, Maryland, Arizona, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Massachusetts, Minnesota, Missouri, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, and Washington.

Additionally, encounters/seizures of these substances have occurred by the CBP at United States ports of entry. As observed by the DEA and CBP, synthetic cathinones originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. From 2014 to 2017, CBP encountered 73 shipments of products containing *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, or 4-chloro-α-PVP. Additional evidence indicates that some of these synthetic cathinones have been seized abroad. *N*-Ethylhexedrone and 4-chloro-α-PVP have been identified in seized materials in China and Poland, respectively. These data demonstrate that these substances are being trafficked and abused in the United States and abroad.

Concerns over the abuse of synthetic cathinone substances have led to the control of many synthetic cathinones. DEA controlled 13 synthetic cathinones: methylone, mephedrone, MDPV, 4-methyl-*N*-ethylcathinone (4–MEC), 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP), *alpha*-pyrrolidinopentiophenone (α-PVP), butylone (1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one), pentedrone (2-(methylamino)-1-phenylpentan-1-one), pentylone, 4-fluoro-*N*-methylcathinone (4–FMC), 3-fluoro-*N*-methylcathinone (3–FMC), naphyrone (1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one), and *alpha*-pyrrolidinobutiophenone (α-PBP) from 2011 to 2014 (October 21, 2011; 76 FR 65371 and March 7, 2014; 79 FR 12938). Recently, DEA controlled another synthetic cathinone, *N*-ethylpentylone (August, 31, 2018; 83 FR 44474), as a schedule I substance.

[5] *See* 76 FR 77330, 77332, Dec. 12, 2011.

[6] Not all exhibits had weights recorded in the NFLIS database.

Factor 6. What, if Any, Risk There Is to the Public Health

Available evidence on the overall public health risks associated with the use of synthetic cathinones suggests that *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP can cause acute health problems leading to emergency department (ED) admissions, violent behaviors causing harm to self or others, or death. Acute adverse effects of synthetic cathinone substances are those typical of sympathomimetic agents (*e.g.,* cocaine, methamphetamine, amphetamine) and include among other effects tachycardia, headache, palpitations, agitation, anxiety, mydriasis, tremor, fever or sweating, and hypertension. Other effects, with possible public health risk implications, that have been reported from the use of synthetic cathinone substances include psychological effects such as psychosis, paranoia, hallucinations, and agitation.

α-PHP, 4–MEAP, MPHP, and PV8 have been associated with the overdoses or deaths of individuals. There have been documented reports of ED admissions or deaths associated with the abuse of α-PHP, 4–MEAP, MPHP, and PV8. Individuals under the influence of 4–MEAP and MPHP have acted violently or unpredictably causing harm, or even death, to themselves or others. Adverse effects associated with α-PHP, 4–MEAP, MPHP, and PV8 abuse included vomiting, agitation, paranoia, hypertension, unconsciousness, tachycardia, seizures, cardiac arrest, rhabdomyolysis, or death. No overdose information is currently available for *N*-ethylhexedrone and 4-chloro-α-PVP, but the pharmacological similarity of these substances to other currently controlled schedule I synthetic cathinones (*e.g.,* methcathinone, mephedrone, methylone, pentylone, MDPV) suggests that these substances can also pose an imminent hazard to public safety.

It remains highly likely that additional cases of adverse health effects involving α-PHP, 4–MEAP, MPHP, and PV8 in the United States may have occurred and will continue to be under-reported as these substances, as well as *N*-ethylhexedrone and 4-chloro-α-PVP, are not part of standard panels for biological specimens. The pharmacological data for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP alone or combined with documented case reports, if any, demonstrate that the potential for fatal and non-fatal overdoses exists for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP; thus, these substances pose an imminent hazard to the public health and safety.

As found with other synthetic cathinone substances, products containing synthetic cathinones often do not bear labeling information regarding the ingredients or the health risks and potential hazards associated with these products. The limited knowledge about product content and its purity, as well as lack of information about its effects, pose additional risks for significant adverse health effects to the users.

Based on pharmacological data or documented case reports of overdose fatalities, the misuse and abuse of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP leads to the same qualitative public health risks as schedule I and II substances such as cathinone, methcathinone, mephedrone, methylone, pentylone, MDPV, methamphetamine, cocaine, and MDMA. α-PHP, MPHP, and PV8 have been associated with fatalities. As the data demonstrates, the potential for fatal and non-fatal overdoses exists for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP; thus, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP pose an imminent hazard to the public safety.

N-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are being encountered on the illicit drug market in the United States and have no accepted medical use in the United States. Regardless, these products continue to be easily available and abused by diverse populations.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP, resulting from the lack of control of these substances, pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP indicate that these synthetic cathinones have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated March 9, 2018, notified the Assistant Secretary of the DEA's intention to temporarily place *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I. DEA published a notice of intent in the **Federal Register** on May 1, 2019. 84 FR 18423.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Acting Administrator considered available data and information, and herein sets forth the grounds for his determination to temporarily schedule *N*-ethylhexedrone (2-(ethylamino)-1-phenylhexan-1-one); *alpha*-pyrrolidinohexanophenone (1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one; *alpha*-pyrrolidinohexiophenone; trivial name: α-PHP); 4-methyl-*alpha*-ethylaminopentiophenone (trivial name: 4–MEAP); 4′-methyl-*alpha*-pyrrolidinohexiophenone (1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one; 4′-methyl-*alpha*-pyrrolidinohexanophenone; trivial name: MPHP); *alpha*-pyrrolidinoheptaphenone (1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one; trivial name: PV8); and 4′-chloro-*alpha*-pyrrolidinovalerophenone (1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one; 4′-chloro-*alpha*-pyrrolidinopentiophenone; trivial name: 4-chloro-α-PVP) in schedule I of the CSA, and finds that placement of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Acting Administrator hereby finds that it is necessary to temporarily place *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling these substances is effective on the date of publication in the **Federal Register**, and is in effect for a period of two years, with a possible extension of one additional year, pending completion of

the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of July 18, 2019. Any person who currently handles *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP, and is not registered with the DEA, must submit an application for registration and may not continue to handle *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP as of July 18, 2019, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after July 18, 2019 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must surrender all currently held quantities of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP.

3. *Security. N*-Ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP are subject to schedule I security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93, as of July 18, 2019.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from July 18, 2019, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312 as of July 18, 2019.

8. *Order Forms.* All DEA registrants who distribute *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 18, 2019.

9. *Importation and Exportation.* All importation and exportation of *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of July 18, 2019.

10. *Quota.* Only DEA registered manufacturers may manufacture *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, and 4-chloro-α-PVP in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of July 18, 2019.

11. *Liability.* Any activity involving *N*-ethylhexedrone, α-PHP, 4–MEAP, MPHP, PV8, or 4-chloro-α-PVP not authorized by, or in violation of the CSA, occurring as of July 18, 2019, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this scheduling order. The specific language chosen by Congress indicates an intention for the DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking. Given that Congress specifically requires the Attorney

General to follow rulemaking procedures for *other* kinds of scheduling actions, *see* section 201(a) of the CSA, 21 U.S.C. 811(a), it is noteworthy that, in section 201(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

In the alternative, even assuming that this action might be subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, ''any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances in schedule I because they pose an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(42) through (47) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(42) *N*-Ethylhexedrone, its optical, positional, and geometric isomers, salts and salts of isomers (Other name: 2-(ethylamino)-1-phenylhexan-1-one) 7246
(43) *alpha*-Pyrrolidinohexanophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: α-PHP; *alpha*-pyrrolidinohexiophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one) 7544
(44) 4-Methyl-*alpha*-ethylaminopentiophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4–MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one) 7245
(45) 4′-Methyl-*alpha*-pyrrolidinohexiophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: MPHP; 4′-methyl-*alpha*-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one) 7446
(46) *alpha*-Pyrrolidinoheptaphenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one) 7548
(47) 4′-Chloro-*alpha*-pyrrolidinovalerophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4-chloro-α-PVP; 4′-chloro-*alpha*-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one) 7443

Dated: July 10, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–15184 Filed 7–17–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0577]

RIN 1625–AA00

Safety Zone; Traverse City Ironman Triathlon, Traverse City, Michigan

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the Captain of the Port, Sault Sainte Marie zone. This rule will provide a temporary safety zone to protect 2,400 participating swimmers in the Traverse City Ironman Triathlon. Entry of vessels into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Sault Sainte Marie.

DATES: This rule is effective from 6:15 a.m. through 9:45 a.m. on August 25, 2019.

ADDRESSES: To view documents mentioned in this preamble as being

available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0577 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email CWO Robert Gruschow Waterways Management, Coast Guard Sector Sault Sainte Marie, U.S. Coast Guard; telephone 906–253–2462.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive the final details of the requested safety zone with sufficient time for a comment period to run before the start of the event. Thus, delaying this rule to wait for a notice and comment period to run would be impracticable and contrary to public interest because it would inhibit the Coast Guard's ability to protect the 2,400 participants from the boating public. It is impracticable to publish an NPRM because we must establish this safety zone by August 25, 2019.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because prompt action is needed to protect the 2,400 swimmers participating in this event on August 25, 2019.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Sault Sainte Marie (COTP) has determined that potential hazards exist while 2,400 participants associated with the Traverse City Ironman Triathlon, swim in a highly congested area of boating traffic between 6:15 a.m. through 9:45 a.m. on August 25, 2019. This rule is needed to protect the 2,400 participates of the Traverse City Ironman Triathlon event.

IV. Discussion of the Rule

On August 25, 2019, Traverse City, Michigan will be hosting an Ironman Triathlon event. The swim course will be in the Southern West Arm of Grand Traverse Bay beginning at the swim coral located west of City Marina and finishing at Clinch Park Beach.

The City of Traverse City will not allow vessels to enter or leave the City's marina which is located inside the safety zone from 6:15 a.m. through 9:45 a.m. on August 25, 2019. Michigan Department of Natural Resources has approved the closure of the marina during the event. This action is only for the temporary safety zone. The Captain of the Port Sault Sainte Marie has determined that there are potential hazards associated with this marine event and a temporary safety zone of 500 yards is needed around the following area, beginning point of 044°46.104 N 085°37.772 W, to the first turn at point 44°46.15.7 N 085°37.48 W to the second turn at point 44°46.70 N 085°36.59 W to the finishing point of 044°45.947 N 085°37.160 W. This rule is needed to protect the 2,400 participants in the navigable waters in the area of the swim course of the Traverse City Ironman Triathlon.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the city of Traverse City's plan in coordination with the state's Department of Natural Resources to close the marina located within the swim course for the duration of the swim event. The Coast Guard's regulatory action will have no impact since state and local authorities are already closing the marina, prior to the establishment of our safety zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 3 and ½ hours that will prohibit any vessel entry within 500 yards of the swim event of the Ironman Triathlon. It is categorically excluded from further review under paragraph L [60] a in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0577 to read as follows:

§ 165.T09–0577 Safety Zone; Traverse City Ironman Triathlon, Traverse City, MI.

(a) *Location.* The temporary safety zone will encompass all U.S. navigable waters of the Southern West Arm of Grand Traverse Bay 500 yards around the following area, beginning at the swim coral located west of City Marina and finishing at Clinch Park Beach, encompassing the following area, beginning point of 044°46.104 N 085°37.772 W, to the first turn at point 44°46.15.7 N 085°37.48 W to the second turn at point 44°46.70 N 085°36.59 W to the finishing point of 044°45.947 N 085°37.160 W.

(b) *Effective and enforcement period.* The regulation in this section is effective and will be enforced from 6:15 a.m. through 9:45 a.m. on August 25, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this temporary safety zone is prohibited unless authorized by the Captain of the Port, Sault Sainte Marie or his or her on-scene representative.

(2) This temporary safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port, Sault Sainte Marie or his on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port, Sault Sainte Marie is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Sault Sainte Marie to act on his or her behalf. The on-scene representative of the Captain of the Port, Sault Sainte Marie will be aboard a Coast Guard vessel.

(4) Vessel Operators desiring to enter or operate within the temporary safety zone shall contact the Captain of the Port, Sault Sainte Marie, or his on-scene representative to obtain permission to do so. The Captain of the Port, Sault Sainte Marie or his or her on-scene representative may be contacted via VHF Channel 16 or at (906) 635–3319. Vessel operators given permission to enter or operate in the temporary safety zone must comply with all directions given to them by the Captain of the Port, Sault Sainte Marie or his or her on-scene representative.

Dated: July 15, 2019.

P.S. Nelson,

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

[FR Doc. 2019–15321 Filed 7–17–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0486]

RIN 1625–AA00

Safety Zone; Ohio River, Brookport, IL

AGENCY: Coast Guard, DHS.

ACTION: Interim final rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone on a portion of the Ohio River in Brookport, IL. This action is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the demolition of Lock and Dam 52 involving explosives. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Ohio Valley or a designated representative.

DATES: This rule is effective without actual notice from July 18, 2019 until December 1, 2019. For the purposes of enforcement, actual notice will be used from July 15, 2019 until July 18, 2019. Comments and related material must be received by the Coast Guard on or before August 19, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0486 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST2, Dylan Caikowski, MSU Paducah, U.S. Coast Guard; telephone 270–442–1621 ext. 2120, email *STL-SMB-MSUPaducah-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable.

It is impracticable to publish an NPRM because this safety zone must be established by July 15, 2019, and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this interim rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the demolition of Lock and Dam 52 involving explosives.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with demolition of Lock and Dam 52 involving explosives will be a safety concern for anyone on the Ohio River from mile marker (MM) 937 to MM 941. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the demolition of Lock and Dam 52 involving explosives.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that covers all navigable waters of the Ohio River from MM 937 to MM 941. This rule will be enforced every day at midday from July 15, 2019 through December 1, 2019 as necessary to facilitate safe demolition of Lock and Dam 52. Broadcast Notices to Mariners (BNMs) will be issued six hours prior to the start of blasting to notify the public that the safety zone is being enforced. Vessels will be able to transit the safety zone when explosives are not being detonated. This safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the detonation of explosives for the demolition. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative during demolition operations involving explosives.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. This safety zone will only be enforced everyday for a short period of time and only impact a small portion of the Ohio River. Additionally, this safety zone will only be enforced in daytime hours during the demolition operations of the Lock and Dam 52.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone for the demolition of Lock and Dam 52 involving explosives on the Ohio River in Brookport, IL. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

VI . Public Participation and Request for Comments

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

We encourage you to submit comments through the Federal eRulemaking Portal at *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.

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

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0486 to read as follows:

§ 165.T08–0486 Safety Zone; Ohio River, Brookport, IL

(a) *Location.* The safety zone will cover all navigable waters of the Ohio River from mile marker (MM) 937 to MM 941.

(b) *Effective period.* This section is effective without actual notice from July 18, 2019 until December 1, 2019. For the purposes of enforcement, actual notice will be used from July 15, 2019 until July 18, 2019.

(b) *Enforcement period.* This section will be enforced every day at midday from July 15, 2019 through December 1, 2019, as necessary to facilitate safe demolition operations.

(c) *Regulations.*

(1) In accordance with the general regulations in § 165.23 of this part, entry of vessels or persons into the zone is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley (COTP) or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Ohio Valley.

(2) Vessels requiring entry into the safety zone must request permission from the COTP or a designated representative. To seek entry into the safety zone, contact the COTP or the COTP's representative by telephone at 502–779–5422 or on VHF–FM channel 16.

(3) Persons and vessels permitted to enter the safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public when the safety zone is being enforced via a Broadcast Notices to Mariners.

Dated: July 12, 2019.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2019–15273 Filed 7–17–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0514]

RIN 1625–AA00

Safety Zone; Cumberland River, Grand Rivers, KY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Cumberland River. This action is necessary to ensure safety of life on these navigable waters immediately prior to, during, and after a pyrotechnics display near Green Turtle Bay Resort, Grand Rivers, KY. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 8:15 p.m. through 9:45 p.m. on August 17, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0514 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email MST2 Dylan Caikowski, MSU Paducah, U.S. Coast Guard; telephone 270–442–1621 ext. 2120, email *STL-SMB-MSUPaducah-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. It is impracticable to publish an NPRM because this safety zone must be established by August 17, 2019, and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with a pyrotechnics display on August 17, 2019, will be a safety concern for anyone within a 420-foot radius of the pyrotechnics display. This rule is needed to protect personnel and vessels in the navigable waters within the safety zone prior to, during, and after a pyrotechnics display.

IV. Discussion of the Rule

This rule establishes a safety zone from 8:15 p.m. until 9:45 p.m. on August 17, 2019. The safety zone will cover all navigable waters within a 420-foot radius from the pyrotechnics launch site at the entrance to Green Turtle Bay Resort at mile marker 31.5 on the Cumberland River in Grand Rivers, KY. The duration of the zone is intended to protect personnel and vessels in these navigable waters prior to, during, and after a pyrotechnic display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a 420-foot radius designated area of the Cumberland River for one hour and thirty minutes on August 17, 2019. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners (BNMs) via VHF–FM marine channel 16 to inform mariners about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only one hour and thirty minutes that will prohibit the entry of vessels and persons within a 420-foot radius of the entrance to Green Turtle Bay Resort at mile marker 31.5 on the Cumberland River in Grand Rivers, KY. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0514 to read as follows:

§ 165.T08–0514 Safety Zone; Cumberland River, Grand Rivers, KY.

(a) *Location.* The safety zone will cover all navigable waters of the Cumberland River at mile marker 31.5 within a 420-foot radius from the fireworks launch site on the Green Turtle Bay Resort in Grand Rivers, KY.

(b) *Enforcement period.* This section will be enforced from 8:15 p.m. through 9:45 p.m. on August 17, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative.

(2) Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or by phone at 502–779–5400.

(3) If permission is granted, all persons and vessels must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of any changes in the planned schedule.

Dated: July 12, 2019.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2019–15272 Filed 7–17–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0567]

RIN 1625–AA00

Safety Zone; Port Huron Float Down, St. Clair River, Port Huron, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the St. Clair River in the vicinity of Port Huron, MI. This zone is intended to restrict and control movement of vessels in a portion of the St. Clair River. Though this is an unsanctioned, non-permitted marine event, this zone is necessary to provide for the safety of life on the navigable waters during a float down event near Port Huron, MI.

DATES: This temporary final rule is effective from 12 p.m. through 8 p.m. on August 18, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0567 in the ''SEARCH'' box and click

''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Tracy Girard, Prevention Department, Sector Detroit, Coast Guard; telephone 313–568–9564, or email *Tracy.M.Girard@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Detroit
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

During the afternoon of August 18, 2019, a non-sanctioned public event is scheduled to take place. The event is advertised over various social-media sites, in which a large number of persons float down a segment of the St. Clair River, using inner tubes and other similar floatation devices. The 2019 float down event will occur between approximately 12 p.m. and 8 p.m. on August 18, 2019. This non-sanctioned event has taken place in the month of August annually since 2009.

No private or municipal entity requested a marine event permit from the Coast Guard for this event, and it has not received state or federal permits since its inception. The event has drawn over 5,000 participants of various ages annually. Despite plans put together by federal, state and local officials, emergency responders and law enforcement officials have been overburdened pursuing safety during this event. Medical emergencies, people drifting across the international border, and people trespassing on residential property when trying to get out of the water before the designated finish line are some of the numerous difficulties encountered during the float down event.

During the 2014 float-down event, a 19-year-old participant died. During the 2016 float down, a wind shift caused thousands of U.S. citizen rafters with no passports to drift into Canadian waters. The current and wind made it impossible for the rafters to paddle back into U.S. waters, necessitating significant coordination with the Canadian authorities. Despite these events, promotional information for the event continues to be published. More than 5,000 people are again anticipated to float down the river this year. No public or private organization holds themselves responsible as the event sponsor.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The Coast Guard did not receive the final details of this float down event in time to publish an NPRM. As such, it is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. Moreover, delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect the public and vessels from the hazards associated with the float down event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Detroit (COTP) has determined the float down poses significant risk to public safety and property from 12 p.m. through 8 p.m. on August 18, 2019. The likely combination of large numbers of participants, strong river currents, limited rescue resources, and difficult emergency response scenarios could easily result in serious injuries or fatalities to float down participants and spectators. Therefore, the COTP is establishing a safety zone around the event location to help minimize risks to safety of life and property during this event.

IV. Discussion of the Rule

This rule establishes a safety zone from 12 p.m. through 8 p.m. on August 18, 2019. The safety zone will begin at Lighthouse Beach and encompass all U.S. waters of the St. Clair River bound by a line starting at a point on land north of Coast Guard Station Port Huron at position 43°00.416′ N; 082°25.333′ W, extending east to the international boundary to a point at position 43°00.416′ N; 082°25.033′ W, following south along the international boundary to a point at position 42°54.500′ N; 082°27.683′ W, extending west to a point on land just north of Stag Island at position 42°54.500′ N; 082°27.966′ W, and following north along the U.S. shoreline to the point of origin (NAD 83). No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Vessel operators must contact the COTP or his or her on-scene representative to obtain permission to transit through this safety zone. Additionally, no one under the age of 18 will be permitted to enter the safety zone if they are not wearing a Coast Guard approved personal floatation device. The COTP or his or her on-scene representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will not be able to safely transit around this safety zone which will impact a small designated area of the St. Clair River from 12 p.m. until 8 p.m. on August 18, 2019. Moreover, the Coast Guard will issue Broadcast Notice to Mariners (BNM) via VHF–FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small

businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting eight hours that will prohibit entry into a designated area. It is categorically excluded from further review under paragraph L[60](a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0567 to read as follows:

§ 165.T09–0567 Safety Zone; Port Huron Float Down, St. Clair River, Port Huron, MI.

(a) *Location.* A safety zone is established to include all U.S. navigable waters of southern Lake Huron and the St. Clair River adjacent to Port Huron, MI, beginning at Lighthouse Beach and encompassing all U.S. waters of the St. Clair River bound by a line starting at a point on land north of Coast Guard Station Port Huron at position 43°00.416′ N; 082°25.333′ W, extending east to the international boundary to a point at position 43°00.416′ N; 082°25.033′ W, following south along the international boundary to a point at position 42°54.500′ N; 082°27.683′ W, extending west to a point on land just north of Stag Island at position 42°54.500′ N; 082°27.966′ W, and following north along the U.S. shoreline to the point of origin (NAD 83).

(b) *Enforcement period.* The regulated area described in paragraph (a) will be in enforced from 12 p.m. through 8 p.m. on August 18, 2019.

(c) *Regulations.* (1) No vessel or person may enter, transit through, or anchor within the safety zone unless authorized by the Captain of the Port Detroit (COTP), or his or her on-scene representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or his or her on-scene representative.

(3) The ''on-scene representative'' of COTP is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the Captain of the Port Detroit to act on his or her behalf.

(4) Vessel operators shall contact the COTP or his or her on-scene representative to obtain permission to enter or operate within the safety zone.

The COTP or his or her on-scene representative may be contacted via VHF Channel 16 or at (313) 568–9560. Vessel operators given permission to enter or operate in the regulated area must comply with all directions given to them by the COTP or his or her on-scene representative.

Dated: July 8, 2019.

Jeffrey W. Novak,

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

[FR Doc. 2019–15282 Filed 7–17–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 49 and 52

[EPA–R10–OAR–2017–0347; FRL–9996–67–Region 10]

Indian Country: Air Quality Planning and Management; Federal Implementation Plan for the Kalispel Indian Community of the Kalispel Reservation, Washington; Redesignation to a PSD Class I Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this final rule, the Environmental Protection Agency (EPA) is approving the May 11, 2017 proposal by the Kalispel Indian Community of the Kalispel Reservation (herein referred to as the Kalispel Tribe of Indians or Kalispel Tribe) to redesignate lands within the exterior boundaries of the Kalispel Indian Reservation located in the State of Washington to Class I under the Clean Air Act (Act or CAA) program for the prevention of significant deterioration (PSD) of air quality. Redesignation to Class I will result in lowering the allowable increases in ambient concentrations of particulate matter (PM), sulfur dioxide (SO_2), and nitrogen oxides (NO_X) on the Kalispel Indian Reservation. Concurrently, the EPA is codifying the redesignation through a revision to the Federal Implementation Plan (FIP) currently in place for the Kalispel Indian Reservation. This FIP will be implemented by the EPA unless or until it is replaced by a Tribal Implementation Plan (TIP).

DATES: This final rule is effective on August 19, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2017–0347. All documents in the docket are listed on the *https://www.regulations.gov* website.

FOR FURTHER INFORMATION CONTACT: Sandra Brozusky at (206) 553–5317, or *brozusky.sandra@epa.gov.*

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

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I. Background

Title 1, part C of the CAA contains the PSD program. The intent of this part is to prevent deterioration of existing air quality in areas having relatively clean air, *i.e.* areas meeting the National Ambient Air Quality Standards (NAAQS). The Act provides for three classifications applicable to all lands of the United States: Class I, Class II, and Class III. Associated with each classification are increments which represent the increase in air pollutant concentrations that would be considered significant. PSD Class I allows the least amount of deterioration of existing air quality. PSD Class II allows a moderate amount of deterioration, while PSD Class III allows the greatest amount of deterioration. Under the 1977 Amendments to the Clean Air Act, all areas of the country that met the NAAQS were initially designated as Class II, except for certain international parks, wilderness areas, national memorial parks and national parks, which were designated as Class I along with any other areas previously designated Class I. The Act allows states and Indian governing bodies to redesignate areas under their jurisdiction to PSD Class I or PSD Class III ''to accommodate the social, economic, and environmental needs and desires of the local population.'' *Arizona* v. *EPA,* 151 F.3d 1205, 1208 (9th Cir. 1998).

On May 11, 2017, the Kalispel Tribe submitted to the EPA an official proposal to redesignate the original Kalispel Reservation from Class II to Class I. The original Kalispel Reservation was established by Executive Order No. 1904, signed by President Woodrow Wilson on March 23, 1914. A copy of this Executive Order is included in the docket for this action. The Kalispel Tribe submitted a supplement to the official proposal on July 13, 2017. The Kalispel Reservation is located in the State of Washington. The Kalispel Tribe's proposal and supplement included an analysis of the impacts of the redesignation within and outside of the proposed Class I area, documentation of the delivery and publication of appropriate notices, a record of the public hearing held on April 10, 2017, and comments received by the Kalispel Tribe on the proposed redesignation. EPA proposed to approve the Kalispel Tribe's proposal to redesignate the original Kalispel Reservation to a Class I area on October 31, 2018. (83 FR 54691). An explanation of the requirements for a redesignation and how the Kalispel Tribe complied with those requirements was provided in the notice of proposed rulemaking and will not be restated here.

The public comment period for this proposed action was open October 31, 2019 through December 14, 2018 and reopened February 5, 2019 through February 20, 2019. EPA held a public hearing on the proposed action on December 6, 2018 in Newport, Washington. During this hearing, 16 members of the public provided verbal comments. Of the 16 verbal commenters, 15 supported EPA's proposed approval of the Kalispel Tribe's redesignation, while one commenter expressed interest in establishing air quality monitoring stations in Pend Oreille County. This comment was determined to be unrelated to this action and no further discussion is provided below. Documentation of these comments is included in the docket for this action.

II. Response to Comments

EPA received comments from 164 parties on the proposed approval of the Kalispel Tribe redesignation request. Of the 164, 137 commenters supported EPA's proposed action, while 17 opposed EPA's proposed action. The remaining ten comments were either unrelated to EPA's proposed approval of the Kalispel Tribe's redesignation request or did not recommend EPA take a position on the redesignation request. In particular, several commenters expressed opposition to the proposed construction of a silicon smelter in Newport, Washington. However, the potential silicon smelter is unrelated to EPA's proposed approval of the Kalispel Tribe's redesignation request. In addition, one commenter provided information on the air quality monitoring needs in Pend Oreille County, but did not connect this information with EPA's proposed approval of the Kalispel Tribe's request. EPA has considered all the relevant comments received. Within this section, we have summarized the adverse comments and provided our responses.

A full copy of comments received is available in the docket for this final action.

A. Economic Impacts of Redesignation

Several commenters argued that EPA should deny the Kalispel Tribe's proposal because redesignating the Kalispel Tribe's original reservation to Class I under the CAA PSD program would hinder economic development in the area. As stated in the proposal, the CAA establishes a narrow role for EPA in reviewing a state or tribe's proposal to redesignate certain areas as either Class I or Class III. Section 164(b)(2) of the CAA states, ''The Administrator may disapprove the redesignation of any area only if he finds, after notice and opportunity for public hearing, that such redesignation does not meet the procedural requirements of [Section 164 of the CAA] or is inconsistent with the requirements of [Section 162(a) of the CAA] (listing mandatory Class I areas).''

Similarly, the United States Court of Appeals for the Ninth Circuit recognized that when Congress amended Section 164 of the CAA in 1977, Congress intended to ''eliminat[e] the authority which EPA had to override a local government's classification of any area on the ground that the local government improperly weighed energy, environment, and other factors.'' *Arizona,* 151 F.3d at 1211 (citing H.R. Rep. No. 95–294, at 7–8). The Ninth Circuit also made clear that once the procedural requirements of Section 164 of the CAA and 40 CFR 52.21 are met, the EPA must approve the request for redesignation. *Id.* at 1208, 1211. The Seventh Circuit has similarly acknowledged that EPA has ''little discretion'' when reviewing redesignation requests, provided the procedural requirements have been met. *Michigan* v. *EPA,* 581 F.3d 524, 526 (7th Cir. 2009) (citing *Arizona,* 151 F.3d at 1208).

Therefore, as described in the statutory text, EPA's role in acting on a state or tribe's proposal is to determine whether the procedural requirements in Section 164 of the CAA and implementing regulations at 40 CFR 52.21(g) have been met, not to assess the prudence of a state or tribe's proposal based on economic considerations or other factors. Moreover, neither the CAA, nor 40 CFR 52.21(g) require a state or tribe requesting redesignation to demonstrate that the redesignation will have no adverse economic, social, or energy effects. As stated in the proposal, EPA found no procedural defects in the Kalispel Tribe's proposed redesignation. Therefore, consistent with the constraints of Section 164 of the CAA and 40 CFR 52.21(g), EPA has determined that approval of the redesignation is appropriate.

B. Consultation With Elected Leadership of Local and Other Substate Governments in the Area Covered by the Proposed Redesignation

Several commenters argued that the regulations governing the process for seeking redesignation mandated that the Kalispel Tribe consult with county-level governments surrounding or near the Kalispel Reservation. The regulation at 40 CFR 52.21(g)(2)(v) provides that ''the State has proposed the redesignation after consultation with the elected leadership of local and other substate general purpose governments in the area covered by the proposed redesignation.'' The regulation at 40 CFR 52.21(g)(4)(i) provides that lands within the exterior boundaries of Indian Reservations may be redesignated if the Indian Governing Body has followed procedures equivalent to those required of a State under 40 CFR 52.21(g)(2).

The Kalispel Tribe's proposal makes clear that the area covered by the proposed redesignation is the original reservation established by Executive Order No. 1904, signed by President Woodrow Wilson on March 23, 1914. The Kalispel Business Council is the exclusive governing authority in the Kalispel Reservation. Therefore, the Kalispel Tribe satisfied this requirement. The area ''covered'' by the redesignation is separate and distinct from the areas that may be ''affected'' by the redesignation. Importantly, the consultation requirement in 40 CFR 52.21(g)(2)(v) is limited only to the areas ''covered'' by the redesignation and does not extend to the areas potentially ''affected'' by the redesignation. As stated in the proposal, there is no consultation requirement for areas that may be affected by the proposed redesignation. By extension, the Kalispel Tribe was not required to consult with county-level governments in Washington or Idaho prior to proposing the redesignation. EPA's evaluation of the Kalispel Tribe's compliance with the procedural requirements at 40 CFR 52.21(g)(2)(v) and 40 CFR 52.21(g)(4)(i) is consistent with the regulatory text.

One commenter stated that because the Kalispel Reservation is located within Pend Oreille County, Pend Oreille County constitutes a local or substate government in the Kalispel Reservation as contemplated by 40 CFR 52.21(g)(2)(v) and 40 CFR 52.21(g)(4)(i). The commenter further stated that EPA's interpretation of 40 CFR 52.21(g)(2)(v), as described in the proposal, undercuts its purpose.

We decline to accept the commenter's interpretation of 40 CFR 52.21(g)(2)(v) to require tribes to consult with substate governments whose boundaries encompass an Indian Reservation. If there existed municipalities or counties within the Kalispel Reservation and the Kalispel Business Council proposed to redesignate lands in those municipalities or counties, then the regulations at 40 CFR 52.21(g)(2)(v) and 40 CFR 52.21(g)(4)(i) would require the Kalispel Business Council to consult with the elected leadership of those municipalities or counties. Here, the Kalispel Business Council is the only governing body with jurisdiction within the Kalispel Reservation. This constitutes an equivalent requirement as that mandated of a state in 40 CFR 52.21(g)(2)(v). Accordingly, this interpretation maintains fidelity to the plain language and purpose of 40 CFR 52.21(g)(4)(i) and (g)(2)(v) and ensures that local and substate governments in the area covered by the redesignation will be consulted prior to a state or tribe proposing redesignation.

C. Inadequate Notice

Three commenters argued that the Kalispel Tribe failed to provide required notice to certain county-level governments potentially impacted by the proposed redesignation. However, EPA does not interpret 40 CFR 52.21(g) or 51.102 as requiring the Kalispel Tribe to provide direct notice of the proposed redesignation to each of these counties individually. As explained in the proposal, and incorporated herein, the Kalispel Tribe satisfied the notification requirements of Section 164 of the CAA and implementing regulations at 40 CFR 52.21(g). The Tribe published a notice of the April 10, 2017, public hearing in the Newport Miner on March 8, 2017, and again on March 15, 2017, as required by 40 CFR 52.21(g)(2)(i). Also, the Tribe directly notified other states, Indian governing bodies, and federal land managers at least 30 days prior to the public hearing as required by 40 CFR 52.21(g)(2)(ii).

As stated above, the Tribe was not required by Section 164 of the CAA, nor the regulations at 40 CFR 52.21(g), to make a finding on what areas may be affected by the proposed redesignation or provide direct notice to such governments in such areas. Nevertheless, on March 6, 2017, the Tribe sent several Pend Oreille County; City of Newport, Washington; Pend Oreille Public Utility District; and Washington Department of Ecology officials a courtesy notice of the Tribe's

intent to propose redesignation, as well as the date, time, and location of the public hearing and the availability of the Kalispel Tribe's February 2017 Class I Redesignation Technical Report (''Technical Report''). Therefore, the Tribe satisfied the notice requirements of the CAA and regulations.

D. Provide a Discussion of the Reasons for the Proposed Redesignation Including a Satisfactory Description and Analysis of the Health, Environmental, Economic, Social, and Energy Effects of the Proposed Redesignation

Several commenters argued that the Kalispel Tribe's Technical Report (Document No. EPA–R10–OAR–2017–0347–0013 in the Docket) failed to provide a satisfactory description and analysis of the economic, social, and energy effects of the proposed redesignation, as required by 40 CFR 52.21(g)(2)(iii). In particular, several commenters stated that the economic analysis provided in the Technical Report inappropriately included data from Spokane County and Stevens County. The commenters argued that the economic situation of Pend Oreille County exclusively was more dire than the regional analysis depicted in the Technical Report and that not all workers living in Pend Oreille County can commute to Spokane.

The statute and regulations do not establish a standard for a ''satisfactory description and analysis of the health, environmental, economic, social, and energy effects of the proposed redesignation. . . .'' 42 U.S.C. 7474(b)(1)(A). The Ninth Circuit's evaluation of a similar criticism of the adequacy of a tribe's analysis is informative. The court stated, ''Congress has established a narrow role for EPA in reviewing State or Tribal requests for redesignation'' and that ''Congress limited EPA's authority to disapprove redesignation requests to a procedural level.'' *Arizona,* 151 F.3d at 1211. Reviewing a challenge to a redesignation, which included the question of whether the Tribe's analysis was ''satisfactory,'' the Court found that EPA ''reasonabl[y] interpret[ed]'' the statutory requirements when the agency concluded that a '' 'satisfactory description and analysis' is a relatively low threshold.'' *Id.*

The court also explained that the CAA ''does not assign any weight to these individual effects and does not suggest that one effect should be given priority over another'' and that Congress did not intend for EPA to ''re-weigh[ ] the effects of a proposed redesignation or second-guess[ ] a Tribe's decision to redesignate its reservation lands.'' *Arizona,* 151 F.3d at 1211–12. Our review of the Technical Report was informed, in part, by the Ninth Circuit's analysis of Section 164(b)(1)(A) of the CAA and we concluded that the analysis was satisfactory. Further, as detailed below, the commenters did not provide information that called into question the factual foundation of the Technical Report.

Specifically, our review of the Technical Report indicated that the Tribe's analysis of the economic impacts of redesignation on Pend Oreille, Stevens, and Spokane Counties was reasonable. In particular, the Technical Report includes a supplemental report as Appendix B entitled ''The Economic Impact of Redesignation of the Kalispel Indian Reservation as a Class I Area under the Clean Air Act's Prevention of Significant Deterioration Program.'' This report included a section entitled ''Defining the Economic Area in Which the Kalispel Tribe is Embedded,'' which explains the Tribe's rationale for defining the Kalispel Reservation Economic Area.

According to this section, the economic analysis included Spokane County and Stevens County because of the economic connections between Pend Oreille County and Stevens County with Spokane County. Pend Oreille County, Spokane County, and Stevens County are located in the Spokane Metropolitan Statistical Area, which is defined by the U.S. Bureau of Economic Analysis based on measured connections between those counties. The section also included data on commuting patterns that indicated 24% of workers in Pend Oreille County commute to Spokane County for work. Commenters did not provide any data to refute these commuting patterns or the economic connections between the counties. Indeed, the propriety of the Tribe's inclusion of Stevens County in the analysis is reinforced by the fact that the Stevens County Commissioners commented on EPA's proposed rulemaking, highlighting the potential economic impacts of redesignation on residents of Stevens County.

The regulation at 40 CFR 52.21(g)(2)(iii) required the Tribe to analyze the economic effects of the proposed redesignation. The regulation does not specify the scope of the analysis. Given the potential for the redesignation to impact pollution sources in Stevens County and Spokane County and the economic linkages between those counties, the Tribe was not unreasonable in analyzing the economic impact of redesignation on all three counties collectively. Moreover, based on the numerous substantive comments the Tribe received regarding the economic situation in Pend Oreille County, the Technical Report appears to have aided the public in providing comments on the Tribe's proposed redesignation.

In addition to the comments regarding the Tribe's economic impacts analysis, one commenter noted that the Technical Report incorrectly accounts for emissions from Ponderay Newsprint Company's facility located less than two miles south of Usk, Washington and inaccurately suggests that Ponderay Newsprint Company's facility accounts for all PM_{10} emissions in the County. However, the Technical Report's description of emissions sources and levels in the area near the Kalispel Reservation is satisfactory.

Specifically, the Technical Report includes a narrative discussion of the sources of emissions in Pend Oreille County and summarized these emissions in Table 13 and Table 14 in the Technical Report. Contrary to the commenter's assertions, the narrative description in the Technical Report makes clear that a sawmill operated by Vaagen Brothers Lumber, Inc. and a locomotive repair facility operated by Pend Oreille Valley Railroad produce particulate emissions in the County, but that information on the precise emissions from these sources was not publicly available. The Tribe also noted in its discussion of emissions sources that the Tribe could not ascertain the status of the air quality permit for Ponderay Newsprint Company's facility. In the alternative, the Tribe obtained emissions estimates for Ponderay Newsprint Company's facility from the Washington Department of Ecology's Title V Program Review Final Report dated September 22, 2014 and provided these estimates in Table 14. Given that the Washington Department of Ecology is the permitting authority for Ponderay Newsprint Company's facility, the Tribe's reliance on these figures is reasonable. The Tribe's decision not to provide an estimate of emissions from other point sources of particulate matter in Table 13 in the absence of a credible source of emissions data was similarly reasonable.

As well as the comments regarding the emissions data presented in the Tribe's Technical Report, three commenters argued that the Technical Report was not satisfactory because it did not include an analysis of the current consumption of the PSD increment for particulate matter with a diameter less than 10 micrometers (PM_{10}). The commenters contend that the absence of this analysis renders the entire Technical Report materially

deficient. We disagree. As stated above, the Kalispel Tribe was required to provide the public, at least 30 days in advance of the public meeting, a discussion of the reasons for the proposed redesignation including a satisfactory description and analysis of the health, environmental, economic, social, and energy effects of the proposed redesignation. The Kalispel Tribe did so. The Kalispel Tribe provided the Technical Report over 30 days in advance of the April 10, 2017, public hearing. As discussed in the proposal, EPA assessed the report and determined that it contains a thorough description of the health, environmental, economic, social, and energy effects of the proposed redesignation.

EPA's assessment is consistent with the limited role assigned to EPA in this endeavor. The Ninth Circuit has recognized that ''Congress has established a narrow role for EPA in reviewing State or Tribal requests for redesignation'' and that ''Congress limited EPA's authority to disapprove redesignation requests to a procedural level.'' *Arizona* v. *EPA,* 151 F.3d at 1211. Reviewing a challenge to a redesignation, which included the question of whether the Tribe's analysis was ''satisfactory,'' the Court found that EPA ''reasonabl[y] interpret[ed]'' the statutory requirements when the agency concluded that a '' 'satisfactory description and analysis' is a relatively low threshold.'' *Id.* Consistent with that direction, given the thorough description and analysis included in the report, it is reasonable for us to conclude that the Kalispel Tribe has cleared this low threshold. Indeed, the Tribe's Technical Report exceeded the minimum requirements in several respects, as discussed below.

Similar to the commenters here, the petitioners in *Arizona* v. *EPA* argued that the Yavapai-Apache Tribe's description and analysis of the potential effects of redesignation was inadequate. *Arizona* v. *EPA,* 151 F.3d at 1212. The Court noted in *Arizona* v. *EPA* that the Tribe's report ''failed to detail what specific effect, if any, redesignation could have on local sources already in existence . . . .'' *Id.* at 1209. The Court nevertheless upheld EPA's approval of the redesignation request on the grounds that the CAA does not mandate a detailed assessment of the impacts of redesignation on existing sources. *Id.* at 1211–12. The Court stated that ''it cannot be said that EPA abused its discretion in concluding that the Tribe was not required, as a prerequisite to redesignation, to go further in its Plan by (1) explicitly balancing the different effects of redesignation; (2) identifying air quality related values; (3) evaluating the extent to which Class I status might discourage particular industrial development and expansion; or (4) pointing to off-site sources which might be impacted by the redesignation, including the Phoenix Cement Plant.'' *Id.* at 1212.

Contrary to the commenters' assertions, the Technical Report at Section 4.1 and Appendix C make clear that the proposed Class I redesignation would reduce the allowable increases above baseline concentration in particulate matter emissions currently allowed under the PSD increment for Class II areas. That is the nature of the Class I PSD redesignation. The commenters are correct that increases in emissions of PM_{10} since the minor source baseline date was triggered consume increment, while decreases in emissions make increment available for future consumption. The emissions increases and decreases contributing to increment consumption fluctuate over time. Moreover, increment consumption is both time- and location-specific—two sources can both consume 100% of the increment if their impact occurs at different locations or different times. An analysis of increment consumption at a fixed point in time, as the commenters request, would not change the overall analysis given these fluctuations.[1]

While determining the current PM_{10} increment consumption in the area in and around the Kalispel Reservation would have provided the public with a snap-shot of the current situation, this determination is not an indispensable component of the description and analysis of the potential impacts of redesignation, as the commenter suggests. Given the temporal and spatial nature of the increments, an analysis of potential impacts would need to include numerous assumptions about future emissions changes and the emissions from future projects. EPA does not interpret the requirement of Section 164 of the CAA and 40 CFR 52.21(g) to provide a ''satisfactory description and analysis'' of potential impacts as requiring such a highly technical and speculative analysis as a prerequisite to obtaining Class I PSD redesignation. As stated above, the Ninth Circuit made clear in *Arizona* v. *EPA* that Section 164 of the CAA does not require a detailed assessment of the impacts of redesignation on existing sources. *Id.* at 1211–12.

Furthermore, the Tribe did provide an assessment of the impact of redesignation on two hypothetical energy projects sited near the Kalispel Reservation. As part of these assessments, the Kalispel Tribe modeled the $PM_{2.5}$, SO_2, and NO_X increment consumption from both hypothetical projects. The assessments modeled consumption of $PM_{2.5}$ increments which are lower than the corresponding PM_{10} increments as a conservative worst-case scenario. The Kalispel Tribe's assessments of the two hypothetical scenarios provide a meaningful analysis of the economic and energy impacts of the proposed redesignation that added value to the public hearing process.

Finally, several commenters argued that the Tribe's Technical Report inaccurately determined that the forest products industry was declining in the area surrounding the reservation and that economic growth in the area is more likely to be driven by sectors other than manufacturing. However, these commenters provided minimal empirical data to refute the Tribe's analysis. Therefore, the Tribe was not unreasonable to structure its analysis of the economic and social impacts of the redesignation around the predicted economic makeup of the region surrounding the Kalispel Reservation. The Tribe provided a satisfactory discussion of the reasons for the proposed redesignation including a satisfactory description and analysis of the health, environmental, economic, social, and energy effects of the proposed redesignation as required by Section 164 of the CAA and 40 CFR 52.21(g)(2)(iii).

E. EPA Should Require the Kalispel Tribe To Redesignate Its Entire Reservation, Not Just a Portion of the Reservation

One commenter argued that EPA should require the Kalispel Tribe to include its entire reservation in the redesignation proposal, rather than just the original reservation. First, neither the CAA nor the regulations at 40 CFR 52.21(g)(4) prohibit a tribe from proposing redesignation of a portion of its reservation. Section 164(c) of the CAA and 40 CFR 52.21(g)(4) state that lands within the exterior boundaries of Indian Reservations may be redesignated only by the appropriate Indian Governing Body. It is reasonable for EPA to read these sections as not

[1] We also note that if the State or EPA determines that an applicable increment is being violated, then the State or EPA is obligated to promulgate a revised implementation plan to correct the violation. However, neither the CAA nor the implementing regulations prescribe how the regulatory authority must act to reduce emissions or what sources the regulatory authority must control. In addition, interested parties will have an opportunity to comment on any plan revisions the State or EPA proposes to correct the increment violation prior to the revisions taking effect.

prohibiting a Tribe from proposing to redesignate only a portion of its reservation, as there is no statutory text indicating that if any part of a Tribe's reservation is redesignated then all of the reservation land must be redesignated.

Contrary to the commenter's statements, EPA's approvals of prior redesignation proposals from other Indian governing bodies is consistent with this interpretation. Indeed, EPA approved the Forest County Potowatomi Community's proposal to redesignate only those parcels in the Community's land that equaled or exceeded 80 acres in size. *See,* 73 FR 23086, 23101 (April 29, 2008). The commenter references EPA's action in approving the Yavapai-Apache Tribal Council's proposal to redesignate the Tribe's entire reservation as support that the CAA requires tribes to propose redesignation of their entire reservations, rather than just a portion of their reservations. 61 FR 56450 (Nov. 1, 1996). However, the action cited by the commenter differs materially from the current action regarding the Kalispel Tribe's proposal. Namely, in the action cited by the commenter, the EPA was required to resolve a dispute between the Governor of Arizona and the Yavapai-Apache Tribe under Section 164(e) of the CAA. 61 FR 56450, 56452. When this dispute resolution procedure is invoked, Section 164(e) of the CAA requires EPA to consider the extent to which the lands involved in the redesignation are of sufficient size to allow effective air quality management or have air quality related values of such an area.

Here, no state has requested EPA resolve any dispute under the authority of section 164(e), and authority to invoke dispute resolution is limited to just states and Indian tribes by the statutory text of section 164(e). Therefore, under Section 164(b) of the CAA, EPA lacks authority to consider whether the lands the Kalispel Tribe has proposed for redesignation are of sufficient size. As stated above, the EPA may disapprove the Kalispel Tribe's request only if the Tribe failed to follow the procedural requirements in Section 164 of the CAA and 40 CFR 52.21(g).

F. Regulatory Flexibility Act

One commenter argued that EPA was required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, to include in the notice of proposed rulemaking an initial regulatory flexibility analysis. In the notice of proposed rulemaking, the Regional Administrator for EPA Region 10 certified pursuant to Section 605 of the RFA that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities. The commenter argues that the Regional Administrator's certification was improper because approval of the Kalispel Tribe's redesignation proposal impacts small entities located near the reservation.

We disagree. The Regional Administrator's certification was proper because EPA's approval of the redesignation does not impose any direct regulatory burden on any small entities. The Regulatory Flexibility Act imposes no obligation for EPA to conduct a small entity impact analysis of effects on entities which EPA does not regulate. As stated in the proposal, the PSD program already exists on the Reservation and the surrounding area. This action merely approves a Tribe's request to redesignate a portion of its reservation to a Class I area under the PSD program and does not impose any direct regulatory obligations on any sources within or surrounding the Reservation. The State of Washington Department of Ecology administers the PSD Program on the lands surrounding the Kalispel Reservation. While the redesignation may impact the State of Washington's planning and permitting decisions, this indirect impact does not constitute direct regulation of small entities. *See Michigan* v. *EPA,* 213 F.3d 663, 689 (D.C. Cir. 2000), *see also Am. Trucking Associations, Inc.* v. *EPA,* 175 F.3d 1027, 1044 (D.C. Cir. 1999).

EPA administers the PSD program on the Kalispel Reservation. Even accepting that approving the Kalispel Tribe's proposal constitutes direct regulation of small entities within the Reservation, there are no permitted stationary sources of emissions within the exterior boundaries of the original Kalispel Reservation. Whether any PSD permits or minor source permits will be issued after the redesignation is speculative, so any effect of the redesignation on any EPA permitting decision is similarly speculative. Therefore, there is insufficient information to conclude that there would be a significant economic impact on a substantial number of small entities located within the Reservation. Accordingly, the Regional Administrator's certification was proper.[2]

G. Other Specific Questions or Comments

Summary: One commenter states that the Clean Air Act did not intend to redesignate areas of land under 5,000 acres.

Response: EPA disagrees. In Section 162(a) of the CAA, Congress initially classified certain areas as Class I under the PSD program, and prohibited redesignation of these areas. Specifically, this section states that all international parks, national wilderness areas which exceed 5,000 acres in size, national memorial parks which exceed 5,000 acres in size, and national parks which exceed six thousand acres in size will be classified as Class I. The 5,000-acre threshold is expressly associated with national wilderness areas and national memorial parks and identifies those areas that are mandatory Class I areas that ''may not be redesignated.'' 42 U.S.C. 7472(a). The statutory text does not establish a size limitation for all Class I areas. Lands of the type identified in Section 162(a) of the CAA that are below the associated size limits are Class II areas by default. Section 164 of the CAA explicitly authorizes states and Indian tribes to redesignate areas as Class I and does not prescribe a size. Neither Section 162 nor Section 164 of the CAA restrict a tribe or state from proposing to redesignate portions of a reservation or state land under 5,000 acres.

Summary: One commenter asserts that a fair and open public hearing held by the Kalispel Tribe never occurred due to the hearing examiner instructing a participant to stop speaking, which discouraged other participants from speaking.

Response: EPA disagrees. In order to allow all participants an opportunity to speak during a public hearing, it is common and appropriate for a hearing examiner or officer to establish a time limit. EPA reviewed this hearing transcript (Document No. EPA–R10–OAR–2017–0347–0029 in the Docket) and determined that the hearing examiner established a three-minute time limit at the beginning of the hearing and enforced this limit during the hearing. Time-limits can be abrupt in nature, however even with the established time limit, the transcript appears to contain full dialogue from participants. All speakers were subject to the same time limit and members of

[2] We also note that this Final Rule amends the FIP for the Kalispel Indian Community for Kalispel Reservation, Washington. codified at 40 CFR 49.10191–49.10220. On April 8, 2005, EPA promulgated this FIP, as well as FIPs for other federally recognized Indian tribes in Washington, Oregon, and Idaho. These FIPs are collectively called the Federal Air Rules for Reservations (''FARR''). See 40 CFR part 49, subpart M and 70 FR 18074. In that rulemaking EPA certified that the promulgation of the FARR would not have a significant economic impact on a substantial number of small entities. 70 FR 18074, 18091–92. Therefore, the Regional Administrator's certification for today's revision to one of the FIPs in the FARR is consistent with the EPA's prior determinations on the impacts of the FARR on small entities.

the public also had the opportunity to submit written comments to the Tribe.

Summary: One commenter asks what effect this designation will have on agricultural field, forest slash, and forest health burning in their community.

Response: We note at the outset that the commenter does not recommend the EPA take a different action than proposed. Therefore, EPA provides the following response for informational purposes only. Emissions increases from the open burning of agricultural field residues or forest slash, and forest health burning after the minor source baseline date may consume the available PSD increment or may expand the increment if such emissions decrease. However, the emissions from these open burning activities are transitory and occur for short durations and at different locations each year. When such emissions are included in increment consumption calculations, we would expect the consumption at any location from such emissions to be small due to the transitory nature of the emissions. Thus, it is unlikely that the redesignation of the Kalispel Indian Reservation to PSD Class I will have an impact on current or future open burning activities.

Summary: One commenter asserts that Boundary County, Idaho is downwind from the Tribal Reservation and the commenter requests that all lands in Boundary County be excluded from the Class I redesignation.

Response: This final action only applies to the area within the external boundaries of the original Kalispel Tribe reservation, as identified in the proposed rule. Boundary County, Idaho will not be redesignated to a Class I area as part of this action.

Summary: Numerous commenters expressed support for EPA's proposed approval of the Kalispel Tribe's redesignation request and encouraged EPA to finalize the approval.

Response: We have considered these comments, acknowledge the support, and agree that finalizing approval of the Kalispel Tribe's redesignation request is appropriate.

III. Final Action

The EPA's review has not found any procedural deficiencies associated with the Kalispel Tribe's proposal. Accordingly, pursuant to section 164 of the CAA and 40 CFR 52.21(g), the redesignation is hereby approved. The EPA is codifying the redesignation through a revision to the FIP currently in place for the Kalispel Indian Reservation. *See* 40 CFR 49.10191–49.10220. This FIP will be implemented by the EPA unless or until it is replaced by a TIP. To ensure transparency, the EPA is also making a clarifying revision to the Washington State Implementation Plan at 40 CFR part 52, subpart WW, which would inform any party interested in Washington's significant deterioration of air quality provisions that the Kalispel Reservation is a Class I area for purposes of prevention of significant deterioration of air quality.

IV. Statutory and Executive Order Reviews

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

This action is not a ''significant regulatory action'' under the terms of the Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the E.O., and was not submitted to the Office of Management and Budget (OMB) for review.

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

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* We are not proposing to promulgate any new paperwork requirements (*e.g.,* monitoring, reporting, record keeping) as part of this action. The regulation at 40 CFR 49.10198 incorporates by reference the Federal PSD program promulgated at 40 CFR 52.21. The OMB has previously approved the information collection requirements contained in the existing regulations (40 CFR 52.21) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* and has assigned OMB control number 2060–0003, EPA ICR number 1230.32.

D. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For the purposes of assessing the impacts of this final action on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field. I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. As stated in Section II, this action will not impose any new requirements on small entities. This action will redesignate to Class I only those lands within the exterior boundaries of the Kalispel Indian Reservation under the CAA's PSD program. The PSD permitting requirements already apply on the Reservation as well as the surrounding area. In addition, the PSD permitting requirements only apply to the construction of new major stationary sources or major modifications to existing major stationary sources. Therefore, the EPA does not anticipate this action having a significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector. Nor does this action create additional requirements beyond those already applicable under the existing PSD permitting requirements.

F. Executive Order 13132: Federalism

This action does not have Federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. This action does not change the relationship between the states and the EPA regarding implementation of the PSD permitting

requirements in the area. The EPA administers the PSD permitting requirements within the Kalispel Reservation. The States of Washington and Idaho administer the permitting requirements in the nearby areas.

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

This action has tribal implications. However, it will neither impose substantial direct compliance costs on Federally-recognized tribal governments, nor preempt tribal law. The EPA is finalizing this action in response to the Kalispel Tribe's proposal to redesignate the Kalispel Reservation from a Class II to a Class I area. Major stationary sources proposed to be constructed within the boundaries of the Kalispel Reservation will be required to demonstrate that the source does not contribute to an exceedance of the lower PSD increments for Class I areas. Nonetheless, pursuant to the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA consulted with tribal officials early in the process of developing this proposed action so that they could have meaningful and timely input into its development. The Kalispel Tribe submitted its proposal on May 11, 2017. Subsequent to receiving the submission, the EPA communicated and corresponded with the Tribe numerous times throughout the review process.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. Redesignation of the Kalispel Indian Reservation to Class I from Class II will reduce the allowable increase in ambient concentrations of various types of pollutants. The reduction of allowable increases in these pollutants can only be expected to better protect the health of tribal members, members of the surrounding communities, and especially children and asthmatics. *See* 78 FR 3086 (regarding the specific human health consequences of exposure to elevated levels of coarse and fine particles); 82 FR 34792 (regarding the specific human health consequences of exposure to elevated levels of nitrogen dioxide); 75 FR 35520 (regarding the specific human health consequences of exposure to elevated levels of sulfur dioxide).

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

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

J. National Technology Transfer and Advancement Act

This action does not involve technical standards. This action merely redesignates the Kalispel Reservation as a Class I area for the purposes of the PSD permitting requirements.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). Prior to this proposal, the EPA reviewed population centers within and around the Kalispel Indian Reservation to identify areas with environmental justice concerns. The results of this review are included in the docket for this action.

Redesignating the Kalispel Indian Reservation will not have an adverse human health or environmental effect on residents within the Reservation or in the surrounding community. On the contrary, by lowering the applicable PSD increments, the redesignation will be more protective of air quality. The following pollutants are subject to the increment requirement: Fine Particulate Matter ($PM_{2.5}$), PM_{10}, SO_2, and Nitrogen Dioxide (NO_2). Exposure to these pollutants is known to have a causal relationship with adverse health effects, such as premature mortality ($PM_{2.5}$, PM_{10}, SO_2), exacerbation of asthma (NO_2 and SO_2), and other respiratory effects (NO_2 and SO_2). *See* 78 FR 3086, 82 FR 34792, and 75 FR 35520. Therefore, a reduction of the allowable concentrations of these pollutants in this area lowers the risk to the surrounding communities of adverse health effects.

L. Congressional Review Act

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).

M. Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 16, 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)).

V. Statutory Authority

The statutory authority for this proposed action is provided by sections 110, 301 and 164 of the CAA as amended (42 U.S.C. 7410, 7601, and 7474) and 40 CFR part 52.

List of Subjects

40 CFR Part 49

Environmental protection, Administrative practice and procedure, Air pollution control, Indians, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 5, 2019.

Chris Hladick,

Regional Administrator, Region 10.

For the reasons stated in the preamble, 40 CFR parts 49 and 52 are amended as follows:

PART 49—INDIAN COUNTRY: AIR QUALITY PLANNING AND MANAGEMENT

■ 1. The authority citation for Part 49 continues to read as follows:

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

Subpart M—Implementation Plans for Tribes—Region X

■ 2. Revise § 49.10198 to read as follows:

§ 49.10198 Permits to construct.

(a) Permits to construct are required for new major stationary sources and major modifications to existing stationary sources pursuant to 40 CFR 52.21.

(b) In accordance with section 164 of the Clean Air Act and the provisions of 40 CFR 52.21(g), the original Kalispel Reservation, as established by Executive Order No. 1904, signed by President Woodrow Wilson on March 23, 1914, is designated as a Class I area for the purposes of prevention of significant deterioration of air quality.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart WW—Washington

■ 4. Amend § 52.2497 by adding paragraph (d) to read as follows:

§ 52.2497 Significant deterioration of air quality.

* * * * *

(d) The regulations at 40 CFR 49.10191 through 49.10220 contain the Federal Implementation Plan for the Kalispel Indian Community of the Kalispel Reservation, Washington. The regulation at 40 CFR 49.10198(b) designates the original Kalispel Reservation, as established by Executive Order No. 1904, signed by President Woodrow Wilson on March 23, 1914, as a Class I area for purposes of prevention of significant deterioration of air quality.

[FR Doc. 2019–15221 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R01–UST–2018–0085; FRL–9996–56–Region 1]

Massachusetts: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the State of Massachusetts' Underground Storage Tank (UST) program submitted by the Massachusetts Department of Environmental Protection (MassDEP). This action also codifies EPA's approval of Massachusetts' state program and incorporates by reference those provisions of the State regulations that we have determined meet the requirements for approval. The provisions will be subject to EPA's inspection and enforcement authorities under sections 9005 and 9006 of RCRA Subtitle I and other applicable statutory and regulatory provisions.

DATES: This rule is effective September 16, 2019, unless EPA receives adverse comment by August 19, 2019. If EPA receives adverse comments, it will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of September 16, 2019, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ADDRESSES: Submit your comments by one of the following methods:

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

2. *Email: coyle.joan@epa.gov.*

3. *Mail:* Joan Coyle, RCRA Waste Management, UST, and Pesticides Section; Land, Chemicals, and Redevelopment Division; EPA Region 1, 5 Post Office Square, Suite 100, (Mail Code 07–1), Boston, MA 02109–3912.

4. *Hand Delivery or Courier:* Deliver your comments to Joan Coyle, RCRA Waste Management, UST, and Pesticides Section; Land, Chemicals, and Redevelopment Division; EPA Region 1, 5 Post Office Square, Suite 100, (Mail Code O07–1), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: Direct your comments to Docket ID No. EPA–R01–UST–2018–0085. EPA's policy is that all comments received will be included in the public docket without change and may be available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov,* or email. The Federal website, *http://www.regulations.gov,* is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and also with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information might not be publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, might be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy.

IBR and supporting material: You can view and copy the documents that form the basis for this codification and associated publicly available materials from 8:30 a.m. to 4:00 p.m. Monday through Friday at the following location: EPA Region 1 Library, 5 Post Office Square, 1st floor, Boston, MA 02109–3912; by appointment only; tel: (617) 918–1990. Interested persons wanting to examine these documents should make

an appointment with the office at least two weeks in advance.

FOR FURTHER INFORMATION CONTACT: Joan Coyle, (617) 918–1303, *coyle.joan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval of Revisions to Massachusetts' Underground Storage Tank Program

A. Why are revisions to state programs necessary?

States that have received final approval from the EPA under RCRA section 9004(b) of RCRA, 42 U.S.C. 6991c(b), must maintain an underground storage tank program that is equivalent to, consistent with, and no less stringent than the Federal UST program. Either EPA or the approved state may initiate program revision. When EPA makes revisions to the regulations that govern the UST program, states must revise their programs to comply with the updated regulations and submit these revisions to the EPA for approval. Program revision may be necessary when the controlling Federal or state statutory or regulatory authority is modified or when responsibility for the state program is shifted to a new agency or agencies.

B. What decisions has the EPA made in this rule?

The responsibility for administering the underground storage tank program was transferred from the Massachusetts Department of Fire Services (DFS) to the Massachusetts Department of Environmental Protection (MassDEP), effective July 1, 2009. The transfer was authorized by the Massachusetts Legislature in Chapter 4 of the Acts of 2009, which also established M.G.L c 21O, *Operation and Removal of Underground Storage Tanks.* On January 2, 2015, MassDEP adopted UST regulations (310 CMR 80.00) that maintained the basic requirements established by DFS (Board of Fire Prevention Regulations 527 CMR 9.00) and authorized by EPA in 1995.

On March 17, 1995, effective April 17, 1995 (60 FR 14371), EPA approved the State's UST program administered by the DFS. Effective December 30, 1996 (61 FR 56135), EPA codified the Massachusetts' statutes and regulations comprising the state's approved UST program, incorporating by reference those approved provisions that EPA could enforce. When the new state UST regulations, 310 CMR 80.00, became effective on January 2, 2015, the existing DFS regulations that were enforceable by EPA were withdrawn. At that time, EPA determined that until the State updates, revises, adopts, and receives approval for their DEP UST regulations to meet the EPA final rule published on July 15, 2015 (80 FR 41566), EPA does not have the authority to enforce the State's current regulations. For that reason, the EPA seeks to approve the revised Massachusetts program at this time and to incorporate by reference those provisions that will be subject to EPA's inspection and enforcement authorities under sections 9005 and 9006 of RCRA and any other applicable statutory provisions. On June 21, 2017, in accordance with 40 CFR 281.51(a), Massachusetts submitted a complete application for final approval of its UST program revisions corresponding to the statutory and regulatory requirements established by Subtitle I of RCRA in effect in 1988, not including those outlined in the EPA final rule that was published on July 15, 2015. EPA concludes that the application and revisions to Massachusetts' UST program are no less stringent than the corresponding federal requirements in subpart C of 40 CFR part 281 promulgated in 1988 and that the Massachusetts program provides for adequate enforcement of compliance with these requirements (40 CFR 281.11(b)). Therefore, the EPA grants Massachusetts approval to operate its UST program with the revisions described in the program approval application.

C. What is the effect of this approval decision?

This action does not impose additional requirements on the regulated community because the regulations being approved by today's rule are already effective in Massachusetts, and they are not changed by today's action. This action merely approves the existing state regulations as meeting the federal requirements and renders them federally enforceable.

D. Why is EPA using a direct final rule?

EPA is publishing this direct final rule concurrent with a proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. EPA is providing an opportunity for public comment now.

E. What happens if the EPA receives comments that oppose this action?

Along with this direct final, the EPA is publishing a separate document in the ''Proposed Rules'' section of this **Federal Register** that serves as the proposal to approve the State's UST program revision, providing opportunity for public comment. If EPA receives comments that oppose this approval, EPA will withdraw the direct final rule by publishing a document in the **Federal Register** before the rule becomes effective. The EPA will base any further decision on the approval of the State program changes after considering all comments received during the comment period. EPA will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this approval, you must do so at this time.

F. For what has Massachusetts previously been approved?

On March 17, 1995, the EPA finalized a rule approving the UST program, effective April 17, 1995, to operate in lieu of the Federal program. On October 31, 1996, effective December 30, 1996, the EPA codified the approved Massachusetts program, incorporating by reference the state statutes and regulatory provisions that are subject to EPA's inspection and enforcement authorities under RCRA sections 9005 and 9006, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions.

G. What changes are we approving with today's action?

On June 21, 2017, in accordance with 40 CFR 281.51(a), Massachusetts submitted a complete application for final approval of its UST program revisions adopted on January 2, 2015. The EPA now makes an immediate final decision, subject to receipt of written comments that oppose this action, that Massachusetts' UST program revision satisfies all of the requirements necessary to qualify for final approval. Therefore, EPA grants Massachusetts final approval for the following program changes:

Required Federal element	Implementing State authority
40 CFR § 281.30, New UST Systems and Notification	310 CMR 80.04; 80.14; 80.16–80.23.
40 CFR § 281.31, Upgrading Existing UST Systems	310 CMR 80.19; 80.21; 80.22.

Required Federal element	Implementing State authority
40 CFR § 281.32, General Operating Requirements	310 CMR 80.03; 80.04; 80.18; 80.22; 80.27; 80.28; 80.29; 80.30; 80.33; 80.36.
40 CFR § 281.33, Release Detection	310 CMR 80.03; 80.04; 80.19; 80.26; 80.31.
40 CFR § 281.34, Release Reporting, Investigation, and Confirmation	310 CMR 80.26; 80.31–80.33; 80.38; 80.39.
40 CFR § 281.35, Release Response and Corrective Action	310 CMR 80.33; 310 CMR 80.38–80.40.
40 CFR § 281.36, Out-of-service Systems and Closure	310 CMR 80.42; 80.43; 310 CMR 80.46; 80.47.
40 CFR § 281.37, Financial Responsibility for USTs Containing Petroleum.	310 CMR 80.04; 80.36; 80.53–80.57; 80.59; 80.60.
40 CFR § 281.40, Legal Authorities for Compliance Monitoring	310 CMR 80.10; 80.13.
40 CFR § 281.41, Legal Authorities for Enforcement Response	310 CMR 80.50.

The State also demonstrates that its program provides adequate enforcement of compliance as described in 40 CFR 281.11(b) and part 281, Subpart D. The MassDEP has broad statutory authority with respect to USTs to regulate installation, operation, maintenance, closure, and UST releases, and to the issuance of orders. These statutory authorities are found in: Massachusetts General Laws, Chapter 21O, Operation and Removal of Underground Storage Tanks; Massachusetts General Laws, Chapter 21E, Massachusetts Oil and Hazardous Material Release Prevention and Response Act; and Massachusetts General Laws, Chapter 21J, Underground Storage Tank Petroleum Product Cleanup Fund.

H. Where are the revised rules different from the Federal rules?

Broader in Scope Provisions

The following statutory and regulatory provisions are considered broader in scope than the federal program, and are therefore not enforceable as a matter of federal law: No underground tank which has been used for the keeping or storage of flammable or combustible fluids shall be removed or relocated unless a permit has first been obtained from the state fire marshal or the official designated by it to grant permits in the city, town or district where such tank is located.

Owners and operators of UST systems containing low level radioactive waste or its mixture with hazardous waste regulated by the Nuclear Regulatory Commission and the Department of Public Health must ensure that the UST systems will prevent releases due to corrosion or structural failure, be cathodically protected against corrosion, be constructed of non- corrodible material, and be constructed or lined with material that is compatible with the stored regulated substance.

Massachusetts requires that consumptive use (CU) tanks of 1,100 gallons or less must comply with release response requirements and, if installed on and after March 21, 2008, be double walled and equipped with continuous interstitial monitoring. Consumptive use tanks greater than 1,100 gallons must comply with most of the regulatory requirements, except financial responsibility and registration. If CU tanks greater than 1,100 gallons were installed before January 1, 1989, they must meet most requirements except the leak detection and the corrosion protection requirements.

Farm and residential tanks having a capacity of 1,100 gallons or less used exclusively for the storage of motor fuel must be double walled and must comply with release response requirements.

Emergency spill or overflow UST systems must be double walled and comply with registration and release response requirements. They must also be emptied within 72 hours of the introduction of regulated substances.

Owners or operators must maintain, until the UST system is removed or permanently closed, a scaled drawing or set of as-built plans prepared by the installer or a registered professional engineer, of all UST systems installed on and after January 2, 2015, with specific information.

Owners and operators of most UST systems are required to hire Third-Party Inspectors (TPIs) to conduct compliance inspections of those systems every three years. MassDEP's TPI Certification Program requires that qualified individuals must pass a written exam and meet certain minimum eligibility requirements, are certified for five years, and need to apply for renewal at least 90 days before their current certifications expire.

Owners or operators of all UST systems must submit a performance-based compliance certification to the Department in accordance with the *Environmental Results Program Certification* requirements.

Owners and operators must ensure that at least one certified Class A, B, and C operator is designated to each UST system.

Massachusetts requires that an owner or operator hire a Licensed Site Professional (LSP) to work on their behalf to oversee the assessment and cleanup of contaminated properties.

Massachusetts provisions that are broader in scope than the federal program are not incorporated by reference and are not part of the federally-approved program.

More Stringent Provisions

The following statutory and regulatory provisions are considered more stringent than the federal program and are therefore enforceable as a matter of federal law:

All single-walled steel tanks in-service and temporarily out-of-service must be permanently closed and removed from the ground, or be permanently closed in-place, by August 7, 2017, except for consumptive use tanks, and tanks that were relined prior to August 8, 2007.

New tanks installed after January 1, 1989, are required to be double walled with interstitial monitoring.

Regulated substance piping installed in UST systems after January 1, 1989, except European suction systems and siphon lines between tanks, are required to be installed with secondary containment.

Groundwater monitoring is not permitted as a form of release detection.

After January 2, 2017, owners and operators may no longer use soil vapor monitoring as a primary form of release detection.

Emergency generator tanks are required to have release detection.

Regulated substance dispensers installed, repaired, or replaced on or after March 21, 2008 must be equipped with a dispenser sump that is continuously monitored with a dispenser sump sensor.

Tanks installed after March 21, 2008, that have a submersible pump must be equipped with a turbine sump that is continuously monitored with a sump sensor.

Turbine, intermediate, and dispenser sumps must pass a tightness test at installation to ensure the sump is liquid tight.

Spill buckets must be at least five gallons in capacity, if installed after

January 2, 2015. Spill buckets must pass a tightness test at installation.

On or after January 2, 2015, new or replacement ball float valves are prohibited from being used as the primary overfill prevention device.

All high-level alarms installed on and after January 2, 2015 must be visible and audible, and be clearly labeled as a tank overfill alarm.

Massachusetts requires all UST systems, regardless of the amount of regulated product received at one time, to have a spill bucket and an overfill prevention device.

All submersible pumps that do not have a turbine containment sump shall be visually inspected every 30 days.

Single-walled and double-walled sumps without continuous monitoring sensors in the sump, and single-walled and double-walled sumps with continuous monitoring that do not meet criteria in 80.27(5)(b)1–(b) 3 must be inspected every 90 days.

All turbine, intermediate and dispenser sumps shall be tested on or before January 2, 2017 to ensure the sump is liquid tight by using vacuum or hydrostatic testing.

Spill buckets must be tested to ensure the spill bucket is liquid tight by using vacuum or hydrostatic testing on or before January 2, 2017 and once every five years thereafter.

Overfill prevention equipment must be inspected and tested as required by the manufacturer's specifications to verify that the overfill protection is operational, or if no manufacturer's specifications exist, annually.

If sacrificial or galvanic anode cathodic protection systems test results indicate a negative voltage of between −0.85 and −0.90, the system shall be tested annually.

Impressed current cathodic protection systems must be tested every 12 months.

All cathodic protection systems must be tested within 60 days of a repair.

Owners or operators of regulated tanks that are not double-walled and do not have continuous monitoring must conduct daily and monthly inventory monitoring, with the exception of emergency generator tanks installed before January 2, 2015.

On and after January 1, 2018, tank and piping/line tightness testing shall be capable of detecting a release or leakage of 0.05 gallon per hour.

Financial responsibility must be maintained and demonstrated for UST systems containing hazardous substances.

When an UST system is taken temporarily out of service, all regulated substances must be removed from the tank and the UST rendered inert. Vent lines must be kept open and functioning and all other lines capped, locked, and secured.

II. Codification

A. What is codification?

Codification is the process of placing a state's statutes and regulations that comprise the state's approved UST program into the CFR. Section 9004(b) of RCRA, as amended, allows the EPA to approve State UST programs to operate in lieu of the Federal program. The EPA codifies its authorization of state programs in 40 CFR part 282 and incorporates by reference state statutes and regulations that the EPA will enforce under sections 9005 and 9006 of RCRA and any other applicable state provisions. The incorporation by reference of state authorized programs in the CFR should substantially enhance the public's ability to discern the current status of the approved state program and state requirements that can be Federally enforced. This effort provides clear notice to the public of the scope of the approved program in each state.

B. What is the history of codification of Massachusetts' UST program?

EPA incorporated by reference the Massachusetts DFS approved UST program effective December 30, 1996 (61 FR 56135; October 31, 1996). In this document, EPA is revising 40 CFR 282.71 to include the approval revision actions.

C. What codification decisions have we made in this rule?

Incorporation by reference: In this rule, we are finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are finalizing the incorporation by reference of the Massachusetts statutes and regulations described in the amendments to 40 CFR part 282 set forth below. The EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 1 office (see the **ADDRESSES** section of this preamble for more information).

The purpose of this **Federal Register** document is to codify Massachusetts' approved UST program. The codification reflects the State program that will be in effect at the time EPA's approved revisions to the Massachusetts UST program addressed in this direct final rule become final. The document incorporates by reference Massachusetts' UST statutes and regulations and clarifies which of these provisions are included in the approved and federally enforceable program. By codifying the approved Massachusetts program and by amending the CFR, the public will more easily be able to discern the status of the federally-approved requirements of the Massachusetts program.

EPA is incorporating by reference the Massachusetts approved UST program in 40 CFR 282.71. Section 282.71(d)(1)(i)(A) incorporates by reference for enforcement purposes the State's statutes and regulations.

Section 282.71 also references the Attorney General's Statement, Demonstration of Adequate Enforcement Procedures, the Program Description, and the Memorandum of Agreement, which are approved as part of the UST program under Subtitle I of RCRA. These documents are not incorporated by reference.

D. What is the effect of Massachusetts' codification on enforcement?

The EPA retains the authority under sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions to undertake inspections and enforcement actions and to issue orders in approved States. With respect to these actions, EPA will rely on federal sanctions, federal inspection authorities, and federal procedures rather than the state authorized analogues to these provisions. Therefore, the EPA is not incorporating by reference such particular, approved Massachusetts procedural and enforcement authorities. Section 282.71(d)(1)(ii) of 40 CFR lists those approved Massachusetts authorities that would fall into this category.

E. What State provisions are not part of the codification?

The public also needs to be aware that some provisions of the State's UST program are not part of the federally approved State program. Such provisions are not part of the RCRA Subtitle I program because they are ''broader in scope'' than Subtitle I of RCRA. 40 CFR 281.12(a)(3)(ii) states that where an approved state program has provisions that are broader in scope than the federal program, those provisions are not a part of the federally approved program. As a result, State provisions which are broader in scope than the federal program are not incorporated by reference for purposes of enforcement in part 282. Section 282.71(d)(1)(iii) of the codification simply lists for reference and clarity the

Massachusetts statutory and regulatory provisions which are broader in scope than the federal program and which are not, therefore, part of the approved program being codified today. Provisions that are broader in scope cannot be enforced by EPA; the State, however, will continue to implement and enforce such provisions under State law.

III. Statutory and Executive Order Reviews

This action only applies to Massachusetts' UST Program requirements pursuant to RCRA Section 9004 and imposes no requirements other than those imposed by State law. It complies with applicable Executive Orders (EOs) and statutory provisions as follows:

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

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). This action approves and codifies State requirements for the purpose of RCRA section 9004 and imposes no additional requirements beyond those imposed by State law. Therefore, this action is not subject to review by OMB.

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

This action is not an Executive Order 13771 (82 FR 9339, February 3, 2017) regulatory action because actions such as today's final approval of Massachusetts' revised underground storage tank program under RCRA are exempted under Executive Order 12866. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

C. Unfunded Mandates Reform Act and Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Because this action approves and codifies pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

D. Executive Order 13132: Federalism

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves and codifies State requirements as part of the State RCRA underground storage tank program without altering the relationship or the distribution of power and responsibilities established by RCRA.

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

This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant, and it does not make decisions based on environmental health or safety risks.

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

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a ''significant regulatory action'' as defined under Executive Order 12866.

G. National Technology Transfer and Advancement Act

Under RCRA section 9004(b), EPA grants a State's application for approval as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State approval application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

H. Executive Order 12988: Civil Justice Reform

As required by Section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

I. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order.

J. Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). ''Burden'' is defined at 5 CFR 1320.3(b).

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this rule approves pre-existing State rules which are at least equivalent to, and no less stringent than existing Federal requirements, and imposes no additional requirements beyond those imposed by State law, and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898.

L. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801–808, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document 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 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). However, this action will be effective September 16, 2019 because it is a direct final rule.

Authority: This rule is issued under the authority of Sections 2002(a), 7004(b), and 9004 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

List of Subjects in 40 CFR Part 282

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Incorporation by reference, Insurance, Intergovernmental relations, Penalties, Petroleum, Reporting and recordkeeping requirements, Surety bonds, Water supply.

Dated: June 20, 2019.

Deborah A. Szaro,

Acting Regional Administrator, EPA Region 1.

For the reasons set forth in the preamble, EPA is amending 40 CFR part 282 as follows:

PART 282—APPROVED UNDERGROUND STORAGE TANK PROGRAMS

■ 1. The authority citation for part 282 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

■ 2. Revise § 282.71 to read as follows:

§ 282.71 Massachusetts State-Administered Program.

(a) The State of Massachusetts is approved to administer and enforce an underground storage tank program in lieu of the federal program under Subtitle I of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6991 *et seq.* The State's program, as administered by the Massachusetts Department Environmental Protection (MassDEP), was approved by EPA pursuant to 42 U.S.C. 6991c and 40 CFR part 281 of this Chapter. EPA approved the Massachusetts program on March 3, 1995, which was effective on April 17, 1995.

(b) Massachusetts has primary responsibility for administering and enforcing its federally approved underground storage tank program. However, EPA retains the authority to exercise its inspection and enforcement authorities under sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, as well as under any other applicable statutory and regulatory provisions.

(c) To retain program approval, Massachusetts must revise its approved program to adopt new changes to the federal Subtitle I program which makes it more stringent, in accordance with section 9004 of RCRA, 42 U.S.C. 6991c and 40 CFR part 281, subpart E. If Massachusetts obtains approval for the revised requirements pursuant to section 9004 of RCRA, 42 U.S.C. 6991c, the newly approved statutory and regulatory provisions will be added to this subpart and notification of any change will be published in the **Federal Register**.

(d) Massachusetts has final approval for the following elements of its program application originally submitted to EPA and approved effective April 17, 1995, and the program revision application approved by EPA, effective on September 16, 2019.

(1) *State statutes and regulations*—(i) *Incorporation by reference.* The material cited in this paragraph, and listed in appendix A to part 282, is incorporated by reference as part of the underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.* (See § 282.2 for incorporation by reference approval and inspection information.) You may obtain copies of the Massachusetts statutes and regulations that are incorporated by reference in this paragraph from the State Bookstore, State House, Room 116, Boston, MA 02133; Phone number: 617–727–2834; Hours: Monday–Friday, 8:45 a.m. to 5:00 p.m.; website: *http://www.sec.state.ma.us/spr/sprcat/catidx.htm.*

(A) ''Massachusetts Statutory and Regulatory Requirements Applicable to the Underground Storage Tank Program, March 2019.''

(B) [Reserved]

(ii) *Legal basis.* EPA evaluated the following statutes and regulations which are part of the approved program, but they are not being incorporated by reference for enforcement purposes, and do not replace Federal authorities:

(A) The statutory provisions include:

(*1*) Massachusetts General Laws, Chapter 21A, *Executive Office of Energy and Environmental Affairs,* Section 16, Civil Administrative Penalties.

(*2*) Massachusetts General Laws, Chapter 21E, *Massachusetts Oil and Hazardous Material Release Prevention and Response Act (2014),* Sections 4 through 6, 8 through 12 and 15 through 18.

(*3*) Massachusetts General Laws, Chapter 21J, *Underground Petroleum Product Cleanup Fund,* Chapters 11 through 14.

(*4*) Massachusetts General Laws, Chapter 21O, *Operation and Removal of Underground Storage Tanks,* Section 4, Sections 6 through 9.

(B) The regulatory provisions include:

(*1*) Code of Massachusetts Regulations, 310 CMR 80, *Underground Storage Tank (UST) Systems:* 80.10 Duty to Provide Information; 80.12 Presumption of Irreparable Harm; 80.13, Department Access to UST Facilities and Records; 80.48, Delivery Prohibition; 80.50, Enforcement and Appeals.

(*2*) Code of Massachusetts Regulations, 310 CMR 40, *Massachusetts Contingency Plan:* 40.0010, Effect of Orders and Appeals; 40.0011, Confidentiality of Information; 40.0013, Presumption of Irreparable Harm; 40.0019, Violations of Environmental Restrictions; 40.0020, Violations of a Permanent Solution or Temporary Solution; 40.0021, Unlawful Interference with Response Actions; 40.0050, Appeals of Orders and Permits; 40.0051, Appeals Relative to Administrative Penalties; 40.0160, Departmental Notice to Responsible Parties and Potentially Responsible Parties; 40.0165, Department Request for Information (RFI); 40.0166, Department Right of Entry; 40.0171, Failure to Perform a Response Action.

(iii) *Provisions not incorporated by reference.* The following specifically identified statutory and regulatory provisions applicable to the Massachusetts' UST program are broader in scope than the federal program, are not part of the approved program, and are not incorporated by reference herein for enforcement purposes:

(A) *Massachusetts General Laws, Chapter 21O: Operation and Removal of Underground Storage Tanks,* Section 1, Removal or relocation of underground flammable or combustible fluid tanks; permits; abandoned underground residential tanks; *Massachusetts General Laws, Chapter 21E: Massachusetts Oil and Hazardous Material Release Prevention and Response Act,* Sections 3A, 3B, Sections 13, 14, and 19 through 22;

(B) *Code of Massachusetts Regulations, Title 310 CMR Chapter 80, Underground Storage Tank Systems:* General Provisions Section, Applicability, 80.04(6)(c), (8) through (12); Design, Construction and Installation Requirements Section, 80.16(7); Requirements for Compliance Certification Section, 80.34; Class A, B, and C Operator Requirements and Certifications, 80.37; Third Party Inspections Section, 80.49; *310 CMR Chapter 40, Massachusetts Contingency Plan:* Subpart B: Organization and Responsibilities, The Role of Licensed

Site Professionals Section, 40.0169; and other provisions of Chapter 40.0000 Subparts A–P insofar as they do not relate to underground storage tanks and with respect to underground storage tanks insofar as they are broader in scope than the federal requirements.

(2) *Statement of Legal Authority.* The Attorney General's Statements, signed by the Attorney General of Massachusetts on August 18, 1993, and March 2, 2017, though not incorporated by reference, are referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(3) *Demonstration of procedures for adequate enforcement.* The ''Demonstration of Procedures for Adequate Enforcement'' submitted as part of the original application on October 5, 1992, and as part of the program revision application for approval on June 21, 2017 though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(4) *Program Description.* The program description and any other material submitted as part of the original application on October 5, 1992, and as part of the program revision application on June 21, 2017, though not incorporated by reference, are referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(5) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region 1 and the Massachusetts Department of Environmental Protection, signed by the EPA Regional Administrator on November 21, 2018 though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

■ 3. Appendix A to part 282 is amended by revising the entry for Massachusetts to read as follows:

Appendix A to Part 282—State Requirements Incorporated by Reference in Part 282 of the Code of Federal Regulations

* * * * *

Massachusetts

(a) The statutory provisions include:

Massachusetts General Laws, Part I, Title II

1. Chapter 21E, *Massachusetts Oil and Hazardous Material Release Prevention and Response Act*

Section 1: Short title; Section 2: Definitions; Section 3: Implementation; regulations; response actions; Section 7: Notice of release or threat of release.

2. Chapter 21O, *Operation and Removal of Underground Storage Tanks*

Section 2: Notification of operation of underground storage tanks; definitions; Section 3: Notification of operation of underground storage tanks; requirements; exceptions; Section 5: Notification of operation of underground storage tanks; regulations for requirements and standards of tanks;

(b) The regulatory provisions include:

1. *Code of Massachusetts Regulations, Title 310 CMR Chapter 80, Underground Storage Tank Systems:* (effective January 2, 2015)

General Provisions Section, 80.01: Authority; 80.02: Purpose; 80.03: Definitions; 80.04: Applicability, (1) through (13), except (6)(c), and (8) through (12); 80.05: Rules of Construction; 80.06: Computation of Time; 80.07: Accurate and Timely Submittals to the Department and Record Keeping; 80.08: Accurate and Complete Record Keeping; 80.09: Accurate Monitoring; 80.11: Submittals to the Department.

Design, Construction and Installation Requirements Section, 80.14: General Requirements; 80.15: General Prohibitions; 80.16: Installation Requirements, except (7); 80.17: Specifications for Tanks; 80.18: Specifications for Regulated Substance Piping; 80.19: Leak Detection; 80.20: Requirements for Turbine, Intermediate and Dispenser Sumps; 80.21: Requirements for Spill Buckets and Overfill Prevention Equipment; 80.22: Requirements for Corrosion Protection.

General Operating Requirements Section, 80.23: Requirements for Registration and Reporting; 80.24: General Requirements; 80.25: Requirements for a UST system or UST Component Emergency Response; 80.26: Requirements for Leak Detection Systems; 80.27: Requirements for Turbine, Intermediate and Dispenser Sumps; 80.28: Requirements for Spill Buckets and Overfill Prevention Equipment; 80.29: Requirements for Corrosion Protection; 80.30: Requirements for Compatibility; 80.31: Requirements for Inventory Monitoring; 80.32: Requirements for Tank and Pipe/Line Tightness Testing; 80.33: Requirements for Repairs and Replacements; 80.35: Requirements for Monthly Inspections; 80.36: Requirements for Recordkeeping.

Leakage and Release: Response, Reporting and Remediation Section, 80.38: Response to a Release; 80.39: Response to Leakage; 80.40: Reportable Releases.

Change-In-Product, Out of Service Systems and Closure Section, 80.41: Requirements for Change-in-product; 80.42: Requirements for Taking a UST System Temporarily Out-of-service; 80.43: Requirements for Removal and Permanent Closure In-place; 80.44: Requirements for Out-of-use UST Systems; 80.45: Requirements for Bringing Out-of-use UST Systems Back into Service; 80.46: Requirements for Previously Closed-in-place UST Systems; 80.47: Standards for Cleaning and Closure.

Financial Responsibility Section, 80.51: Definitions; 80.52: Requirements for Amount and Scope of Financial Responsibility; 80.53: Allowable Mechanisms and Combinations of Mechanisms; 80.54: Requirements for Financial Responsibility Mechanisms; 80.55: Requirements for a Standby Trust; 80.56: Substitution of Financial Assurance Mechanisms by Owner or Operator; 80.57: Cancellation or Nonrenewal by a Provider of Financial Assurance; 80.58: Requirements for Reporting by Owner or Operator; 80.59: Requirements for Recordkeeping; 80.60: Requirements for Drawing on Financial Assurance Mechanisms; 80.61: Release from Financial Responsibility Requirements; 80.62: Bankruptcy or Other Incapacity of Owner or Operator or Provider of Financial Assurance; 80.63: Requirements for Replenishment of Local Government Guarantees, Letters of Credit, or Surety Bonds.

2. *Code of Massachusetts Regulations, Title 310 CMR Chapter 40: Massachusetts Contingency Plan* (effective April 24, 2014) only insofar as they pertain to the regulation of underground storage tanks in Massachusetts and only insofar as they are incorporated by reference and are not broader in scope than the federal requirements. Note that reserved sections of 310 CMR 40.0000 *et seq.* are not incorporated by reference:

Subpart A: General Provisions, except 40.0010 through 40.0013, 40.0016, 40.0019 through 40.0021, 40.0050, 40.0051; Subpart B: Organization and Responsibilities, except 40.0160, 40.0165, 40.0166, 40.0169, 40.0171); Subpart C: Notification of Releases and Threats of Release of Oil and Hazardous Material; Identification and Listing of Oil and Hazardous Material; Subpart D: Preliminary Response Actions and Risk Reduction Measures; Subpart E: Tier Classification and Response Action Deadlines; Subpart H: Comprehensive Response Actions; Subpart I: Risk Characterization; Subpart J: Permanent and Temporary Solutions; Subpart K: Audits; Subpart L: Cost Recovery, Lien Hearings and Petitions for Reimbursement of Incurred Costs; Subpart M: Administrative Record; Subpart N: Public Involvement and Technical Assistance Grants.

(c) Official copies of the Massachusetts statutes and regulations that are incorporated by reference, are available at: State Bookstore, State House, Room 116, Boston, MA 02133; Phone number: 617–727–2834; Hours: Monday–Friday, 8:45 a.m. to 5:00 p.m.; website: *http://www.sec.state.ma.us/spr/sprcat/catidx.htm.*

* * * * *

[FR Doc. 2019–15226 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket Nos. 17–317, 17–105; FCC 18–166]

Electronic Delivery of MVPD Communications; Modernization of Media Regulation Initiative

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, an information collection associated with the rules regarding electronic delivery of MVPD communications contained in the Commission's *Report and Order* in MB Docket Nos. 17–317 and 17–105, FCC 18–166. This document is consistent with the *Report and Order,* which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of the rules.

DATES: The *addition of* § 76.1600 and the amendments to §§ 76.1614 and 76.1619, published at 83 FR 66149, December 26, 2018, are effective July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Kim Matthews, Media Bureau at (202) 418–2154. For additional information concerning the Paperwork Reduction Act information collection requirements contact Cathy Williams at (202) 418–2918 or via email: *cathy.williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Commission submitted revised information collection requirements for review and approval by OMB, as required by the Paperwork Reduction Act (PRA) of 1995. They were approved by OMB on July 9, 2019. The information collection requirements are contained in the Commission's *Report and Order, Electronic Delivery of MVPD Communications, Modernization of Media Regulation Initiative,* FCC 18–166 published at 83 FR 66149, December 26, 2018. The OMB Control Numbers are 3060–0652 and 3060–0548. The Commission publishes this document as an announcement of the effective date of the rules published December 26, 2018. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C854, 445 12th Street SW, Washington, DC 20554. Please include the OMB Control Number in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on July 9, 2019 for the information collection requirements contained in new rule 47 CFR 76.1600 and the changes to 47 CFR 76.1614 and 47 CFR 76.1619, adopted in the *Report and Order* published at 83 FR 66149, December 26, 2018. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Numbers are 3060–0652 and 3060–0548.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Pub. L. 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0652.

OMB Approval Date: July 9, 2019.

OMB Expiration Date: July 31, 2020.

Title: Section 76.309, Customer Service Obligations; Section 76.1600, Electronic Delivery of Notices; Section 76.1602, Customer Service—General Information, Section 76.1603, Customer Service—Rate and Service Changes and 76.1619, Information and Subscriber Bills.

Form Number: N/A.

Respondents: Business or other for-profit entities; State local or Tribal Government.

Number of Respondents and Responses: 4,113 respondents; 1,109,246 responses.

Estimated Time per Response: 0.0.167—1 hour.

Frequency of Response: On occasion reporting requirement and Third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 154(j), 325, 338, 624A, 631, 632, and 653.

Total Annual Burden: 41,796 hours.

Total Annual Cost: No Cost. Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

OMB Control Number: 3060–0548.

OMB Approval Date: July 9, 2019.

OMB Expiration Date: June 30, 2020.

Title: Cable Television System Signal Carriage Obligation Recordkeeping: Section 76.1708, Principal Headend; Sections 76.1709 and 76.1620, Availability of Signals; Section 76.1614, Identification of Must-Carry Signals; Section 76.56, Signal Carriage Obligations.

Form Number: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 4,103 respondents; 49,236 responses.

Estimated Time per Response: 0.5–1 hours.

Frequency of Response: Recordkeeping requirement, Third party disclosure requirement, On occasion and annual reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154(i), 614 and 615.

Total Annual Burden: 24,618 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On November 15, 2018, the Commission adopted an order modernizing its rules regarding certain information that cable operators are required to provide to their subscribers on paper. The order permitted these notices to instead be provided electronically via verified email, so long as the cable operator complies with certain consumer safeguards. The order also permitted electronic delivery of subscriber privacy information that cable operators and other multichannel video programming distributors (MVPDs) are required to provide and authorized cable operators to respond to consumer requests and complaints via email in certain circumstances. The Commission has received OMB approval for the information collections required by the order. The Commission therefore revises these information collections to reflect the changes made in the order.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–15287 Filed 7–17–19; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 190325272–9537–02]

RIN 0648–XG925

Pacific Island Pelagic Fisheries; 2019 U.S. Territorial Longline Bigeye Tuna Catch Limits

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

ACTION: Final specifications.

SUMMARY: In this final rule, NMFS specifies a 2019 limit of 2,000 metric tons (t) of longline-caught bigeye tuna for each U.S. Pacific territory (American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI)). NMFS will allow each territory to allocate up to 1,000 t each year to U.S. longline fishing vessels in a valid specified fishing agreement. As an accountability measure, NMFS will monitor, attribute, and (if necessary) restrict catches of longline-caught bigeye tuna, including catches made under a specified fishing agreement. These catch limits and accountability measures support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: The final specifications are effective July 17, 2019, through December 31, 2019. The deadline to submit a specified fishing agreement pursuant to 50 CFR 665.819(b)(3) for review is August 19, 2019.

ADDRESSES: Copies of the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (Pelagic FEP) are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org.*

NMFS prepared environmental analyses that describe the potential impacts on the human environment that would result from the action. Copies of those analyses, which include an environmental assessment (EA) and a finding of no significant impact (FONSI), are available from *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0028,* or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Rebecca Walker, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION: NMFS is specifying a catch limit of 2,000 t of longline-caught bigeye tuna for each U.S. Pacific territory in 2019. NMFS is also authorizing each territory to allocate up to 1,000 t of its 2,000 t bigeye tuna limit to U.S. longline fishing vessels permitted to fish under the Pelagic FEP. Those vessels must be identified in a specified fishing agreement with the applicable territory. NMFS will monitor catches of longline-caught bigeye tuna by the longline fisheries of each territory, including catches made by U.S. longline vessels operating under specified fishing agreements. The criteria that a specified fishing agreement must meet, and the process for attributing longline-caught bigeye tuna, will follow the procedures in 50 CFR 665.819. When NMFS projects that a territorial catch or allocation limit will be reached, NMFS will, as an accountability measure, prohibit the catch and retention of longline-caught bigeye tuna by vessels in the applicable territory (territorial catch limit), and/or vessels in a specified fishing agreement (allocation limit).

You may find additional background information on this action in the preamble to the proposed specifications published on June 6, 2019 (84 FR 26394).

Comments and Responses

On June 6, 2019, NMFS published the proposed specifications and request for public comments (84 FR 26394); the comment period closed on June 21, 2019. NMFS received seven comments from three commenters, and discusses and responds to these comments below. No changes have been made from the proposed specifications in response to the comments. We note that one technical correction has been made in the final EA, as described below in the response to Comment 7.

In addition, in light of the decision in *Territory of American Samoa* v. *NMFS, et al.* (16–cv–95, D. Haw), NMFS specifically invited public comments on the effect of the proposed action on cultural fishing in American Samoa. NMFS received no comments addressing cultural fishing.

Comment 1: NMFS should consider lowering the annual totals, and consider heavier regulation against longline fishing practices in the Pacific.

Response: In developing the territorial bigeye tuna catch allocation limits, NMFS and the Council considered a range of catch and allocation limits, taking into consideration sustainability of the stock, decisions of regional fishery management organizations, and the needs of Pacific Island fishing communities. The 2019 allocation limits allow for the sustainability of the bigeye tuna stock and are consistent with the Pelagic FEP, the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and other applicable laws.

Comment 2: NMFS should act thoughtfully and quickly in completing this rulemaking process. In past years, the deep-set fishery in the Western and Central Pacific Ocean (WCPO) and the Eastern Pacific Ocean (EPO) attained the U.S. bigeye tuna catch limits in each area. As a result, many U.S. deep-set vessels were unable to fish because they were not able to allocate catch pursuant to already-executed specified fishing agreements. Such delays in rulemaking impede the achievement of the goals of the Pelagic FEP. The publication of the proposed rule earlier in the calendar year in 2019 should ensure no closure period of fishing operations in the WCPO.

Response: NMFS reviews the proposed catch and allocation limits for consistency with the provisions of the Magnuson-Stevens Act, the Pelagic FEP, decisions of the WCPFC, and other applicable laws. This review requires preparation of comprehensive supporting environmental analyses to ensure the conservation of affected fish stocks and protected species. While NMFS is committed to preparing analyses before the fishery could reach the WCPO bigeye tuna limit, NMFS also encourages the domestic fishing industry to consider industry-led actions in both the WCPO and the EPO that might reduce the likelihood of reaching a catch limit, or that would otherwise alleviate the impact of a closure.

Comment 3: The proposed rule will provide substantial benefits for the U.S. territories, the Hawaii-based longline fisheries, the Hawaii seafood market, and protected species.

Response: NMFS agrees that this action, which is identical to the catch and allocation limits implemented in 2014 (79 FR 64097, October 28, 2014), 2015 (80 FR 61767, October 14, 2015; 80 FR 68778, November 6, 2015), 2016 (81 FR 63145, September 14, 2016), 2017 (82 FR 47642, October 13, 2017), and 2018 (83 FR 53399, October 23, 2018), addresses the conservation and management needs of bigeye tuna in the WCPO, and considers the needs of fishing communities of the U.S. Pacific Islands, and the impacts to protected species.

Comment 4: Transferred effects caused by closing Hawaii-based longline fisheries have detrimental impacts on local Hawaii seafood markets and on protected species that are caught more frequently by foreign fisheries.

Response: NMFS considered the concept of transferred effects during a closure of the U.S. longline fleet in the development of these specifications and the EA.

Comment 5: The specifications will not affect WCPO bigeye tuna stock status.

Response: NMFS is satisfied that this action is consistent with the conservation and management needs of bigeye tuna in the WCPO. The catch and allocation limits would not result in a change in stock status of WCPO bigeye tuna.

Comment 6: The proposed limits are substantially more stringent than conservation measures adopted by WCPFC, which do not establish any bigeye limits for the territories. The commenter questioned whether there is a necessity to limit each territory to a 1,000 t allocation.

Response: This action implements the recommendation from the Council's 176th meeting, in March 2019. The Council recommended that NMFS specify a 2,000 t longline bigeye catch limit for each U.S. participating territory, and that NMFS specify that each territory can allocate up to 1,000 t of their bigeye catch limit. Utilizing the best scientific information available, NMFS has determined that these catch and allocation limits are consistent with WCPFC objectives. NMFS acknowledges that the WCPFC has not adopted bigeye limits for the U.S. territories. NMFS notes that the Council has recommended amending the Pelagic FEP and Federal regulations to remove the requirement that NMFS must first specify catch limits for the territories before specifying allocation limits, but a plan amendment and proposed regulations to implement this Council recommendation have yet to be developed.

Comment 7: The commenter is supportive of the conclusion that the effect of the action on Endangered Species Act (ESA)-listed marine mammal species is insubstantial. The EA should include the information that there has never been an observed interaction in the very small area of overlap between the area in which Hawaii longline fishing effort occurs and the designated range of the main Hawaiian islands (MHI) insular stock of false killer whales, as Table 32 in the EA incorrectly implies that there have been continued observed interactions with MHI insular false killer whales.

Response: NMFS acknowledges that observers have not documented interactions in the area of overlap between the area in which fishing effort occurs and the designated range of the MHI insular stock of false killer whales. Therefore, NMFS has made a technical correction to Table 32 in section 3.3.2.1 of the final EA.

Classification

The Regional Administrator, NMFS Pacific Islands Region, determined that this action is necessary for the conservation and management of Pacific Island fishery resources, and that it is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is exempt from review under Executive Order 12866.

Because this rule relieves a restriction, the exception in 5 U.S.C. 553(d)(1) applies so that it is not subject to the 30-day delayed effectiveness provision of the Administrative Procedure Act. This rule allows U.S. vessels identified in a valid specified fishing agreement to resume fishing in the WCPO even if NMFS closes the longline fishery for bigeye tuna. Consistent with Conservation and Management Measure 2018–01 adopted by the WCPFC at its December 2018 meeting, the bigeye tuna catch limit applicable to U.S. longline fisheries in the WCPO in 2019–2020 is 3,554 t. When NMFS projects that the limit will be reached, NMFS must close the fishery for bigeye tuna in the WCPO. Regulations at 50 CFR 665.819 require NMFS to begin attributing longline caught bigeye tuna to the U.S. territory to which a fishing agreement applies either seven days before the date NMFS projects that the fishery will reach the WCPO U.S bigeye tuna limit, or upon the effective date of the agreement, whichever is later. Based on longline catch records to date, NMFS projects the current 3,554 t limit of WCPO bigeye tuna will be reached on August 29, 2019. This projected date is subject to change, and the projected date throughout 2019 has continued to fall earlier in the year as the fishing year has progressed. If the effectiveness of this final rule is delayed past the date that the WCPO bigeye tuna limit is reached, NMFS would be required to publish a temporary rule that restricts the retention of WCPO bigeye tuna in the Hawaii-based longline fishery until this final rule is effective. After the effective date, NMFS would remove the restrictions for U.S. vessels identified in a valid specified fishing agreement with a U.S. territory. Implementing this rule immediately allows the fishery to continue fishing without the uncertainty or disruption of a potential closure.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule would not have a significant economic impact on a substantial number of small entities. NMFS published the factual basis for the certification in the proposed rule, and we do not repeat it here. NMFS received no comments on this certification; as a result, a final regulatory flexibility analysis is not required, and none has been prepared.

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

Dated: July 15, 2019.

Samuel D. Rauch III,

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

[FR Doc. 2019–15317 Filed 7–17–19; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 138
Thursday, July 18, 2019

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

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0460]

Public Hearings on Liquefied Gas Carriers Transiting Through San Juan Harbor, San Juan, PR

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meetings.

SUMMARY: The Coast Guard announces two public meetings to receive comments regarding the safe navigation and mooring of liquefied natural gas carriers through the San Juan Harbor, San Juan PR.

DATES: The public meetings will be held from 1:00 p.m. to 3:00 p.m., and from 5:00 p.m. to 7:00 p.m. on July 26, 2019 to provide an opportunity for verbal comments. Written comments and related material may also be submitted to Coast Guard personnel specified at that meeting. All comments and related material submitted after the meeting must be received by the Coast Guard on or before August 4, 2019.

ADDRESSES: The public meetings will be held at Sheraton Puerto Rico Hotel and Casino, 200 Convention Boulevard, San Juan, PR 00907, (787) 993–3500.

Comment submission: You may submit comments associated with docket number USCG–2019–0460 using the Federal eRulemaking Portal at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you have any questions concerning the meeting, please call or email LCDR Pedro Mendoza, Sector San Juan Prevention Department, Waterways Management Division, U.S. Coast Guard; telephone 787–729–2374, email *Pedro.L.Mendoza@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Coast Guard Sector San Juan and New Fortress Energy will be hosting public meetings on July 26, 2019 from 1:00 p.m. to 3:00 p.m., and from 5:00 p.m. to 7 p.m., for the general public to provide comments regarding the proposed adjustment to the current safety zone established under 33 CFR 165.754, ''Safety Zone: San Juan Harbor, San Juan, PR''.

On Dec. 12, 2017, the U.S. Coast Guard received a Letter of Intent and Waterway Suitability Assessment from New Fortress Energy to construct and operate the required infrastructure for offloading and transferring liquefied natural gas at the Army Terminal Turning Basin in San Juan, Puerto Rico. After reviewing New Fortress Energy's request and providing recommendations, on September 26, 2018, the Coast Guard Sector San Juan determined the Port of San Juan is suitable for the proposed operation.

These public meetings will allow attendees to submit comments on the proposed safety zone adjustment. The proposed amendment is intended to address the operation of LNG gas carriers and add the new facility within the San Juan Harbor, San Juan, PR.

We encourage you to participate by submitting comments either verbally at the meeting or in writing. If you bring written comments to the meeting, you may submit them to Coast Guard personnel specified at the meeting to receive written comments. These comments will be submitted to our online public docket. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided.

Comments submitted after the meeting must reach the Coast Guard on or before August 4, 2019. We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact LCDR Pedro Mendoza at the telephone number or email address provided under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Dated: July 12, 2019.

E. P. King,

Captain, U.S. Coast Guard, Captain of the Port San Juan.

[FR Doc. 2019–15267 Filed 7–17–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R01–UST–2018–0085; FRL–9996–55–Region 1]

Massachusetts: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is proposing to approve revisions to the State of Massachusetts' Underground Storage Tank (UST) program submitted by the Massachusetts Department of Environmental Protection (MassDEP). This action is based on EPA's determination that these revisions satisfy all requirements needed for program approval. This action also proposes to codify EPA's approval of Massachusetts' state program and to incorporate by reference those provisions of the State regulations that we have determined meet the requirements for approval. The provisions will be subject to EPA's inspection and enforcement authorities under sections 9005 and 9006 of RCRA subtitle I and other applicable statutory and regulatory provisions.

DATES: Send written comments by August 19, 2019.

ADDRESSES: Submit any comments, identified by EPA–R01–UST–2018–0085, by one of the following methods:

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

2. *Email: coyle.joan@epa.gov.*

3. *Mail:* Joan Coyle, RCRA Waste Management, UST, and Pesticides Section; Land, Chemicals, and Redevelopment Division; EPA Region 1, 5 Post Office Square, Suite 100, (Mail Code 07–1), Boston, MA 02109–3912.

4. *Hand Delivery or Courier:* Deliver your comments to Joan Coyle, RCRA Waste Management, UST, and Pesticides Section; Land, Chemicals, and Redevelopment Division; EPA Region 1, 5 Post Office Square, Suite 100, (Mail Code 07–1), Boston, MA 02109–3912.

Instructions: Direct your comments to Docket ID No. EPA–R01–UST–2018–0085. EPA's policy is that all comments received will be included in the public docket without change and may be available online at *http://www.regulations.gov.* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov,* or email. The Federal *http://www.regulations.gov.* Website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

You can view and copy the documents that form the basis for this codification and associated publicly available materials from 8:30 a.m. to 4:00 p.m. Monday through Friday at the following location: EPA Region 1 Library, 5 Post Office Square, 1st floor, Boston, MA 02109–3912; by appointment only; tel: (617) 918–1990. Interested persons wanting to examine these documents should make an appointment with the office at least two weeks in advance.

FOR FURTHER INFORMATION CONTACT: Joan Coyle, (617) 918–1303; email address: *coyle.joan@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Authority: This rule is issued under the authority of Sections 2002(a), 9004, and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

Dated: June 20, 2019.

Deborah A. Szaro,

Acting Regional Administrator, EPA Region 1.

[FR Doc. 2019–15225 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 380, 383, and 384

[Docket No. FMCSA–2007–27748]

RIN 2126–AC25

Partial Extension of Compliance Date for Entry-Level Driver Training

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking; extension of compliance date.

SUMMARY: FMCSA proposes to amend its December 8, 2016, final rule, ''Minimum Training Requirements for Entry-Level Commercial Motor Vehicle Operators'' (ELDT final rule), by extending the compliance date for two provisions from the rule. The date for training providers to upload entry-level driver training (ELDT) certification information into the Training Provider Registry (TPR) and for State Driver Licensing Agencies (SDLAs) to receive driver-specific ELDT information would be extended from February 7, 2020, to February 7, 2022. This action would provide FMCSA additional time to complete development of the electronic interface that will receive and store ELDT certification information from training providers and transmit that information to the SDLAs. The proposed extension would also provide SDLAs with sufficient time to modify their information technology (IT) systems and procedures, as necessary, to accommodate their receipt of driver-specific ELDT data from the TPR.

DATES: Comments on this notice must be received on or before August 19, 2019.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2007–27748 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments, including collection of information comments for the Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, Driver and Carrier Operations (MC–PSD) Division, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 by telephone at 202–366–4325 or by email at *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking (NPRM) is organized as follows:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this NPRM (Docket No. FMCSA–2007–27748), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2007–27748, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is customarily not made available to the general public by the submitter. Under the Freedom of Information Act, CBI is exempt from public disclosure. If you have CBI that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Accordingly, please mark each page of your submission as ''confidential'' or ''CBI.'' Submissions designated as CBI and meeting the definition noted above will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Analysis Division, 1200 New Jersey Avenue SE, Washington, DC 20590. Any commentary that FMCSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2007–27748, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

D. Waiver of Advance Notice of Proposed Rulemaking

Under the Fixing America's Surface Transportation Act, Public Law, 114–94 (FAST Act), FMCSA is required to publish an advance notice of proposed rulemaking (ANPRM) or conduct a negotiated rulemaking ''if a proposed rule is likely to lead to the promulgation of a major rule'' (49 U.S.C. 31136(g)(1)). As this proposed rule is not likely to lead to the promulgation of a major rule, the Agency is not required to issue an ANPRM or to proceed with a negotiated rulemaking.

II. Executive Summary

A. Purpose and Summary of the Proposed Rule

FMCSA proposes to extend the compliance date for two provisions from the final rule, ''Minimum Training Requirements for Entry-Level Commercial Motor Vehicle Operators'' (81 FR 88732, Dec. 8, 2016) (ELDT final rule) from February 7, 2020, to February 7, 2022. The proposed two-year extension would delay the date by which training providers must begin uploading driver-specific training certification information into the Training Provider Registry (TPR), an electronic database that will contain entry-level driver training (ELDT) information. It would also delay the date by which State Driver Licensing Agencies (SDLAs) must confirm that applicants for a commercial driver's license (CDL) have complied with ELDT requirements prior to taking a specified knowledge or skills test. The extension would give FMCSA time to complete the IT infrastructure for the TPR to allow for the upload, storage, and transmission of the driver-specific training records. It would also provide SDLAs time to make changes, as necessary, to their IT systems and internal procedures that would allow them to receive the driver course completion information transmitted from the TPR. The Agency proposes to extend the compliance date at this time, so that SDLAs and other stakeholders can take the proposed delay into account when setting budget and resource allocation priorities. In proposing this delay, FMCSA is also proposing clarifying and conforming changes to the regulations established by the ELDT final rule.

FMCSA does not propose any other substantive changes to the requirements established by the ELDT final rule. This means that, beginning February 7, 2020, training providers wishing to provide ELDT must be listed on the TPR and drivers seeking a CDL or endorsement on or after February 7, 2020, must complete the required training, as set forth in the ELDT final rule.

B. Costs and Benefits

The Agency estimates that this proposed rule would result in annualized cost savings over a three-year period of $8.06 million at a 3% discount rate and $10.13 million at a 7% discount rate.

III. Abbreviations and Acronyms

AAMVA American Association of Motor Vehicle Administrators
ANPRM Advance Notice of Proposed Rulemaking
BTW Behind the Wheel
CDL Commercial Driver's License
CDLIS Commercial Driver's License Information System
CFR Code of Federal Regulations
CMV Commercial Motor Vehicle
CMVSA Commercial Motor Vehicle Safety Act
DOT U.S. Department of Transportation
ELDT Entry-Level Driver Training
E.O. Executive Order
FMCSA Federal Motor Carrier Safety Administration
FMCSRs Federal Motor Carrier Safety Regulations
FR Federal Register
FRFA Final Regulatory Flexibility Analysis
IT Information Technology
NEPA National Environmental Policy Act of 1969
NPRM Notice of Proposed Rulemaking
OMB Office of Management and Budget
PIA Privacy Impact Assessment
PII Personally Identifiable Information
PRA Paperwork Reduction Act
RIA Regulatory Impact Analysis
RIN Regulation Identifier Number
SDLA State Driver Licensing Agency
SORN Systems of Records Notice
§ Section symbol
TPR Training Provider Registry
U.S.C. United States Code

IV. Legal Basis for the Rulemaking

The legal basis of the ELDT final rule, set forth at 81 FR 88738–88739, also serves as the legal basis for this NPRM. A brief summary of the statutory authorities identified in that discussion follows. FMCSA's authority to amend the ELDT final rule by extending the compliance date for two requirements and making other necessary clarifying and conforming changes, as proposed, is derived from several concurrent statutory sources. The Motor Carrier Act of 1935, as amended, codified at 49 U.S.C. 31502(b), authorizes the Secretary of Transportation (the Secretary) to prescribe requirements for the safety of motor carrier operations. The NPRM also relies on the provisions of the Motor Carrier Safety Act of 1984, as amended, codified at 49 U.S.C. 31136(a)(1) and (2), requiring the Secretary to establish regulations to ensure that commercial motor vehicles (CMVs) are operated safely, and that responsibilities placed on CMV drivers do not impair their ability to safely operate CMVs. The NPRM does not address medical standards for drivers or physical effects related to CMV driving (49 U.S.C. 31136(a)(3) and (4)). The Agency does not anticipate that drivers will be coerced as a result of this proposal (49 U.S.C. 31136(5)). The Commercial Motor Vehicle Safety Act of 1986 (CMVSA), as amended, codified generally in 49 U.S.C. chapter 313, established the commercial driver's license (CDL) program and required the Secretary to promulgate implementing regulations, including minimum standards for testing and ensuring the fitness of an individual operating a commercial motor vehicle (49 U.S.C. 31305(a)). The specific statutory provision underlying the ELDT final rule, enacted as part of The Moving Ahead for Progress in the 21st Century Act and codified at 49 U.S.C. 31305(c), required the Secretary to establish minimum entry-level driver training standards for certain individuals required to hold a CDL.

The Administrator of FMCSA is delegated authority under 49 CFR 1.87 to carry out the functions vested in the Secretary by 49 U.S.C. chapters 311, 313, and 315, as they relate to CMV operators, programs, and safety.

V. Background

The ELDT final rule established minimum training standards for individuals applying for a Class A or Class B CDL for the first time; individuals upgrading their CDL to a Class B or Class A; and individuals obtaining the following endorsements for the first time: Hazardous materials (H), passenger (P), and school bus (S). The final rule also defined curriculum standards for theory and behind-the-wheel (BTW) instruction for Class A and B CDLs and the P and S endorsements, and theory instruction requirements for the H endorsement. Additionally, the rule required that SDLAs verify ELDT completion before allowing the applicant to take a skills test for a Class A or Class B CDL, or a P or S endorsement; or a knowledge test prior to obtaining the H endorsement.

The final rule also established the TPR, an online database which would allow ELDT providers to electronically register with FMCSA and certify that individual driver-trainees completed the required training. The rule set forth eligibility requirements for training providers to be listed on the TPR, including a certification, under penalty of perjury, that their training programs meet those requirements. The final rule, when fully implemented, will require training providers to enter driver-specific ELDT information, which FMCSA will then verify before transmitting to the SDLA. The process is designed to deliver a finished ''product'' (*i.e.,* verified driver-specific ELDT information) to the end user, the SDLA. The NPRM is therefore consistent with the Agency's position that full implementation of the final rule presumes an integrated electronic system used concurrently by training providers, FMCSA, and the SDLAs. As FMCSA stated in the ELDT final rule, SDLAs will not be required to accept paper training certificates as evidence of ELDT completion.[1]

In adopting the February 7, 2020, compliance date for the ELDT final rule, FMCSA noted that several changes to the ELDT NPRM, published on March 7, 2016 (81 FR 11944), reduced the regulatory implementation burden on SDLAs. For example, the final rule dropped the proposed requirement for refresher training, which would have required SDLAs to issue restricted CDLs so that the BTW portion of the training could be completed on public roads. FMCSA also removed the proposed requirements that SDLAs verify the applicant received ELDT from a provider listed on the TPR and maintain a separate record of the applicant's training certification information. These provisions, if retained in the ELDT final rule, would have required more extensive IT modifications by the SDLAs. FMCSA therefore believed, in light of the simplified requirements, that the TPR and State-based systems could be integrated and operational by the February 7, 2020, compliance date, allowing adequate time for the States to pass implementing legislation and modify their technology platforms as necessary. Unfortunately, due to unanticipated delays in completing the entire IT infrastructure for the TPR, FMCSA concludes that the compliance date of February 7, 2020, must be extended to February 7, 2022, for the two provisions discussed above in section II.A, ''Purpose and Summary of the Proposed Rule.''

FMCSA previously acknowledged that the American Association of Motor Vehicle Administrators (AAMVA) and individual SDLAs, in comments submitted to the NPRM, raised important questions and concerns regarding transmittal of the applicant's ELDT information through the Commercial Driver's License Information System (CDLIS). Accordingly, the Agency said that it ''will work closely with AAMVA and the SDLAs during the implementation

[1] *See* 81 FR 88732, 88767 (Dec. 8, 2016)

phase to address these issues in a way that minimizes the administrative burden on States to the greatest extent possible.'' [2] FMCSA continues to follow that approach and remains actively engaged with AAMVA to identify the most efficient means of transmitting the ELDT certification information to the SDLAs.

VI. Discussion of Notice of Proposed Rulemaking (NPRM)

Today's NPRM proposes a new compliance date of February 7, 2022, for two provisions from the ELDT final rule: the requirement that training providers upload driver-specific training certification information to the TPR, and the requirement that SDLAs confirm driver applicants are in compliance with the ELDT requirements prior to taking a skills test for a Class A or Class B CDL, or a passenger (P) or school bus (S) endorsement, or prior to taking the knowledge test to obtain the hazardous materials (H) endorsement. The proposed two-year extension of the compliance date of these two requirements, from February 7, 2020, to February 7, 2022, is necessary to allow the Agency time to complete full functionality for the TPR and to establish the electronic means by which the ELDT certification information will be transmitted to the SDLAs. The proposed extension would also permit the SDLAs time to make necessary modifications to their IT systems that would allow them to receive ELDT certification information from the TPR, and to adopt required procedural changes to ensure the information is used in accordance with the ELDT final rule. The Agency requests comment on the proposed two-year extension of the compliance date for the two provisions discussed above.

The proposed extension of the compliance date does not apply to any other provision from the ELDT final rule, which retains the initial compliance date of February 7, 2020. This means that by February 7, 2020, in order to be listed on the TPR, a training provider must meet the applicable eligibility requirements set forth in 49 CFR part 380, subpart G, and electronically register with the TPR, which will include affirming, under penalty of perjury, that the provider meets the eligibility requirements and will, at a minimum, follow the FMCSA-prescribed curriculum for the CDL class or endorsement. Although the TPR will not be able to accept or transmit the ELDT training certification information needed for SDLAs to confirm that drivers are meeting their training requirements, training providers listed on the TPR would remain subject to the documentation and recordkeeping requirements set forth in § 380.725, beginning February 7, 2020. The Agency intends to permit training providers to begin electronic registration prior to the compliance date of February 7, 2020. FMCSA will provide additional guidance on the TPR registration process before the registration period opens.

Additionally, beginning February 7, 2020, driver applicants must complete the training required in 49 CFR part 380, subpart F, and comply with the requirements of 49 CFR 383.71(a)(3), (b)(11), and (e)(5), prior to obtaining any of the following commercial license credentials for the first time: A Class A or Class B CDL; an upgrade to a Class B or a Class A CDL; or an H, P, or S endorsement. Driver applicants must obtain ELDT from a training provider listed on the TPR. The TPR will be accessible to driver applicants who need to identify a registered training provider that meets their needs.

VII. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, United States territories). Motor carriers and drivers are subject to the laws and regulations of the countries in which they operate, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences among nations.

VIII. Section-by-Section Analysis

FMCSA proposes to revise section 380.717 by changing the compliance date for training providers to electronically transmit training certification information to the TPR from February 7, 2020, to February 7, 2022. In section 383.73, paragraphs (b)(11) and (e)(9), FMCSA proposes to change the compliance date from February 7, 2020, to February 7, 2022. This would delay by two years the date by which a State must verify the applicant has completed the required ELDT. The Agency also proposes to revise section 384.230 by changing the compliance date from February 7, 2020, to February 7, 2022. This date identifies when a State must comply with the requirements of sections 383.73(b)(11) and (e)(9). In addition, current paragraph (b) of section 384.230 would be deleted in conformance with the change in the States' compliance date. As a result of that change, current paragraph (a) would be designated as section 384.230. Finally, the NPRM would revise section 384.301(k) by requiring States to come into substantial compliance with the ELDT-related requirements of sections 383.73 and 384.230 no later than February 7, 2022.

Unrelated to the delayed compliance date for these portions of the final rule, FMCSA also proposes to make several clarifying changes to existing ELDT-related requirements in section 383.73. In paragraphs (b)(3) and (b)(3)(ii), the proposal would remove references to the State performing a check for whether the applicant has completed required training prior to initial issuance of the CDL. This proposed change reflects that, as intended by the ELDT final rule, the threshold for the SDLA's verification that an applicant completed the required ELDT is at the point of skills testing or, in the case of the H endorsement, knowledge testing. This proposed change would therefore eliminate what would otherwise be a duplicative requirement inadvertently imposed on the States; the requirement that States verify the applicant received ELDT training before conducting skills testing is already set forth in section 383.73(b)(11). Similarly, the NPRM would revise paragraph (e)(9) to clarify that the State must verify an applicant's completion of required ELDT at the point of testing, not issuance.

IX. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA performed an analysis of the impacts of the proposed rule and determined it is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review. Accordingly, the Office of Management and Budget (OMB) has not reviewed it under that Order. It is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.6 dated Dec. 20, 2018).

As discussed above, this proposed rule would delay, until February 7, 2022, the compliance date of two provisions from the ''Minimum Training Requirements for Entry-Level Commercial Motor Vehicle Operators'' Final Rule (81 FR 88732, Dec. 8, 2016), (ELDT final rule). The two provisions proposed for delay are the requirement that training providers electronically transmit training certification information to the TPR, and the

[2] 81 FR 88767 (Dec. 8, 2016).

requirement that States verify the applicant has completed the required ELDT. This proposed rule would not impact any other substantive requirement of the ELDT final rule, which retains the compliance date of February 7, 2020.

Because FMCSA proposes to delay the implementation of these two provisions of the ELDT final rule to 2022, this regulatory evaluation presents the costs that would not be realized in years 2020–2021. Because the Agency does not propose any changes to the training requirements of the ELDT final rule, this NRPM would not impact the benefits enumerated in the ELDT final rule.

As a result of the two-year delay, SDLAs and training providers would experience marginal cost savings in years 2020 and 2021, with no changes to the costs presented in the 2016 Regulatory Impact Analysis that accompanied the ELDT final rule (2016 RIA) for years 2022–2029. The Agency presents the costs relative to the baseline of the ELDT final rule.

In the ELDT final rule, FMCSA assumed that SDLAs would incur costs related to IT system modifications necessary to allow them to receive the ELDT certification information and use it in accordance with the ELDT final rule. Because this proposed rule would shift the SDLAs' compliance date by two years, we conclude that any assumed costs by the SDLAs would also be shifted two years, to 2022 rather than 2020. This change is merely a temporal shift of a cost assumed as part of the 2016 RIA for the ELDT final rule.

FMCSA estimated in the 2016 RIA that in 2020 this IT system upgrade would cost $1.2 million per SDLA, and therefore $60 million,[3] across all 51 SDLAs. FMCSA acknowledged in the 2016 RIA that, while some of these costs may be incurred prior to the effective date of the rule, FMCSA applied this entire cost to the first year of the analysis (2020). As noted above, the proposed rule shifts these costs from 2020 to 2022, which would result in a cost savings to SDLAs of $1.21 million annualized over three years at a 3% discount rate and $2.88 million at a 7% discount rate. These estimates of cost savings represent the sum across all 51 SDLAs.

In the 2016 RIA, FMCSA estimated that training providers would incur costs starting in 2020 for submitting training certificate information to the TPR. FMCSA estimates that this proposed rule, by deferring these training provider costs to 2022, would result in cost savings to training providers of $6.84 million at a 3% and $7.25 million at a 7% discount rate on an annualized basis over three years.[4]

The Agency estimates that this proposed rule would result in total annualized cost savings over a three-year period of $8.06 million at a 3% discount rate and $10.13 million at a 7% discount rate.

B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)

E.O. 13771 was issued on January 30, 2017 (82 FR 9339, Feb. 3, 2017).

This proposed rule is expected to have total costs less than zero and would qualify as an E.O. 13771 deregulatory action if finalized. The present value of the cost savings of this proposed rule, measured on an infinite time horizon at a 7% discount rate, expressed in 2016 dollars, and discounted to 2020 (the year the proposed rule would go into effect and cost savings would first be realized), is $18 million. On an annualized basis, these cost savings are $1 million.

For the purpose of E.O. 13771 accounting, the April 5, 2017, OMB guidance requires that agencies also calculate the costs and cost savings discounted to year 2016. In accordance with this requirement, the present value of the cost savings of this rule, measured on an infinite time horizon at a 7% discount rate, expressed in 2016 dollars, and discounted to 2016, is $14 million. On an annualized basis, these cost savings are $1 million.

C. Regulatory Flexibility Act (Small Entities)

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000 (5 U.S.C. 601(6)). Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses.

As part of the ELDT final rule, FMCSA prepared a Final Regulatory Flexibility Analysis (FRFA). As noted in that FRFA, the ELDT final rule would affect all entities that choose to become training providers. Accordingly, this NPRM would also affect all entities choosing to become training providers. As shown in the FRFA,[5] FMCSA estimated that approximately 4.6 million small entities could employ entry-level drivers, but that only 22,000 entities would register with FMCSA to become training providers. The impact of this NPRM on those entities that choose to become training providers would be even less than the $500 in the first year that the 2016 RIA estimated, as the costs for the first year of this NPRM would now only include costs for uploading individual entry-level driver training certifications, as registering in the TPR will have already been completed as required by the ELDT final rule. As the full $500 first year cost estimate used in the 2016 RIA and FRFA was determined to be less than 1% of revenues for entities in any of the potentially affected industries, the same would be the case for any cost estimate lower than $500. Therefore, I certify that the proposed action would not have a significant economic impact on a substantial number of small entities.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this NPRM so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance; please consult the FMCSA point of contact, Mr. Richard Clemente listed in the **FOR FURTHER INFORMATION CONTACT** section of this NPRM. Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's

[3] The 2016 final RIA estimated costs and benefits in 2014 dollars. All estimates in this analysis have been updated from 2014 dollars to 2018 dollars using a multiplier of 1.065. The GDP deflator for 2014 is 103.680 and the deflator for 2018 is 110.389. 110.389/103.680 = 1.065. This is based on Implicit Price Deflators for Gross Domestic Product (GDP) from on the Bureau of Economic Analysis (BEA) archive of National Accounts (NIPA) data that were initially published on March-1-2019 in connection with the Initial estimates for 2018 Q4. Accessed April 2019 at *https://apps.bea.gov/histdata/fileStructDisplay.cfm?HMI=7&DY=2018&DQ=Q4&DV=Initial&dNRD=March-1-2019. Using* estimates updated to 2018 dollars, 51 SDLAs × $1,171,180 = $59,730,159.

[4] The 2016 RIA annualized costs over the ten-year period estimated. As this proposed rule would be shifting costs out to begin in 2022, FMCSA annualized costs over 2020, 2021, and 2022.

[5] Section 5 of the 2016 RIA.

Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. The Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $161 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2017 levels) or more in any one year. This proposed rule would not result in such an expenditure. However, the Agency does discuss the economic effects of this NPRM in section VIII, subsections A. and B., above.

F. Paperwork Reduction Act

This proposed rule would call for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The 2016 ELDT final rule discussed the changes to the approved collection of information, but did not revise the supporting statement for that collection at that time, because the changes from the final rule would not take effect until after the expiration date of that approved collection (see PRA discussion at 81 FR 88732, 88788). This collection is currently being revised as part of its renewal cycle, and as required by the PRA (44 U.S.C. 3507(d)), FMCSA will submit its estimate of the burden of the proposal contained in this NPRM to the Office of Management and Budget (OMB) for its review of the collection of information renewal, and will provide notice and an opportunity for public comment on the estimate. It is the agency's intent to obtain OMB approval for the revised collection of information in advance of the February 7, 2020, compliance date for training providers under the 2016 ELDT final rule, to allow them time to complete the TPR registration process prior to February 7, 2020.

G. E.O. 13132 (Federalism)

A rule has implications for Federalism under Section 1(a) of Executive Order 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' FMCSA determined that this proposal would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Impact Statement.

H. E.O. 12988 (Civil Justice Reform)

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. E.O. 13045 (Protection of Children)

E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, Apr. 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this proposed rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

J. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this proposed rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it would not effect a taking of private property or otherwise have taking implications.

K. Privacy

The Consolidated Appropriations Act, 2005, (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note) requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. This rule does not change the collection of personally identifiable information (PII) as set forth in the 2016 ELDT final rule. The supporting PIA, available for review on the DOT website, *http://www.transportation.gov/privacy,* gives a full and complete explanation of FMCSA practices for protecting PII in general and specifically in relation to the ELDT final rule, which would also cover this proposed action.

As required by the Privacy Act (5 U.S.C. 552a), FMCSA and DOT will publish, with request for comment, a system of records notice (SORN) that will describe FMCSA's maintenance and electronic transmission of information affected by the requirements of the ELDT final rule that are covered by the Privacy Act. This SORN will be developed to reflect the new storage and electronic transmission of information and will be published in the **Federal Register** not less than 30 days before the Agency is authorized to collect or use PII retrieved by unique identifier.

L. E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this NPRM.

M. E.O. 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

N. E.O. 13175 (Indian Tribal Governments)

This rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

O. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

P. Environment

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) requires Federal agencies to integrate environmental values into their decision-making processes by considering the potential environmental impacts of their actions. In accordance with NEPA, FMCSA's NEPA Order 5610.1 (NEPA Implementing Procedures and Policy for Considering Environmental Impacts), and other applicable requirements, FMCSA prepared an Environmental Assessment (EA) to review the potential impacts of the ELDT final rule. That EA is available for inspection or copying in the *Regulations.gov* website listed under **ADDRESSES**.

Because this NPRM would only delay the compliance date of portions of the ELDT final rule without any other substantive change to the regulations, FMCSA proposes to continue to rely upon the previously published EA to support this NPRM. As noted in that EA, implementation of the ELDT final rule would impose new training standards for certain individuals applying for their CDL, an upgrade of their CDL, or hazardous materials, passenger, or school bus endorsement for their license. FMCSA found that noise, endangered species, cultural resources protected under the National Historic Preservation Act, wetlands, and resources protected under Section 4(f) of the Department of Transportation Act of 1966, 49 U.S.C. 303, as amended by Public Law 109–59, would not be impacted. The impact areas that may be affected and are evaluated in the EA include air quality, hazardous materials transportation, solid waste, and public safety. But the impact area of focus for the EA is air quality. Specifically, as outlined in the 2016 RIA for the ELDT final rule, FMCSA anticipated that an increase in driver training will result in improved fuel economy based on changes to driver behavior, such as smoother acceleration and braking practices. Such improved fuel economy is anticipated to result in lower air emissions and improved air quality for gases, including carbon dioxide. FMCSA expects that all negative impacts, if any, will be negligible. However, we expected the overall environmental impacts of the ELDT final rule to be beneficial.

Q. E.O. 13783 (Promoting Energy Independence and Economic Growth)

E.O. 13783 directs executive departments and agencies to review existing regulations that potentially burden the development or use of domestically produced energy resources, and to appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources. In accordance with E.O. 13783, DOT prepared and submitted a report to the Director of OMB that provides specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency action that burden domestic energy production. This proposed rule has not been identified by DOT under E.O. 13783 as potentially alleviating unnecessary burdens on domestic energy production.

List of Subjects

49 CFR Part 380

Administrative practice and procedure, Highway safety, Motor carriers, Reporting and recordkeeping requirements.

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor Carriers.

49 CFR Part 384

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

For the reasons set forth in the preamble, FMCSA proposes to amend 49 CFR parts 380, 383, and 384 as follows:

PART 380—SPECIAL TRAINING REQUIREMENTS

■ 1. The authority citation for part 380 continues to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31305, 31307, 31308, 31502; sec. 4007(a) and (b), Pub. L. 102–240, 105 Stat. 1914, 2151; sec. 32304, Pub. L. 112–141, 126 Stat. 405, 791; and 49 CFR 1.87.

■ 2. Amend § 380.717 by revising the introductory text to read as follows:

§ 380.717 Training certification.

Beginning on February 7, 2022, after an individual completes training administered by a provider listed on the TPR, that provider must, by midnight of the second business day after the driver-trainee completes the training, electronically transmit training certification information through the TPR including the following:

* * * * *

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 3. The authority citation for part 383 continues to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 *et seq.,* and 31502; secs. 214 and 215 of Pub. L 106–159, 113 Stat. 1748, 1766, 1767; sec. 1012(b) of Pub. L. 107–56; 115 Stat. 272, 297, sec. 4140 of Pub. L. 109–59, 119 Stat. 1144, 1746; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; secs. 5401 and 7208 of Pub. L. 114–94, 129 Stat. 1312, 1546, 1593; and 49 CFR 1.87.

■ 4. Amend § 383.73 by revising paragraph (b)(3) introductory text, paragraphs (b)(3)(ii), (b)(11), and (e)(9) to read as follows:

§ 383.73 State procedures.

* * * * *

(b) * * *

(3) Initiate and complete a check of the applicant's driving record to ensure that the person is not subject to any disqualification under § 383.51, or any license disqualification under State law, and does not have a driver's license from more than one State or jurisdiction. The record check must include, but is not limited to, the following:

* * * * *

(ii) A check with the CDLIS to determine whether the driver applicant already has been issued a CDL, whether the applicant's license has been disqualified, or if the applicant has been disqualified from operating a commercial motor vehicle;

* * * * *

(11) Beginning on February 7, 2022, not conduct a skills test of an applicant for a Class A or Class B CDL, or a passenger (P) or school bus (S) endorsement, until the State verifies electronically that the applicant completed the training prescribed in subpart F of part 380 of this subchapter.

* * * * *

(e) * * *

(9) Beginning on February 7, 2022, not conduct a skills test of an applicant for an upgrade to a Class A or Class B CDL, or a passenger (P), school bus (S) endorsement, or administer the knowledge test to an applicant for the hazardous materials (H) endorsement, unless the applicant has completed the training required by subpart F of part 380 of this subchapter.

* * * * *

PART 384—STATE COMPLIANCE WITH COMMERCIAL DRIVER'S LICENSE PROGRAM

■ 5. The authority citation for part 384 continues to read as follows:

Authority: 49 U.S.C. 31136, 31301 *et seq.,* and 31502; secs. 103 and 215 of Pub. L. 106–59, 113 Stat. 1753, 1767; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 5401 and 7208 of Pub. L. 114–94, 129 Stat. 1312, 1546, 1593; and 49 CFR 1.87.

■ 6. Revise § 384.230 to read as follows:

§ 384.230 Entry-level driver certification.

Beginning on February 7, 2022, a State must comply with the requirements of § 383.73(b)(11) and (e)(9) to verify that the applicant completed the training prescribed in subpart F of part 380.

■ 11. Amend § 384.301 by revising paragraph (k) to read as follows:

§ 384.301 Substantial compliance-general requirements.

* * * * *

(k) A State must come into substantial compliance with the requirements of subpart B of this part and part 383 of this chapter in effect as of February 6, 2017, as soon as practicable but not later than February 7, 2022.

* * * * *

Issued under the authority of delegation in 49 CFR 1.87.

Raymond P. Martinez,

Administrator.

[FR Doc. 2019–14956 Filed 7–17–19; 8:45 am]

BILLING CODE 4910–EX–P

Notices

Federal Register
Vol. 84, No. 138
Thursday, July 18, 2019

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

AGENCY FOR INTERNATIONAL DEVELOPMENT

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request

AGENCY: U.S. Agency for International Development.

ACTION: Notice of information collection.

SUMMARY: U.S. Agency for International Development (USAID), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the following new information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested concerning (1) Whether the proposed collection of information is necessary for the sustaining USAID-funded programming beyond USAID funding; (2) the accuracy of USAID's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents.

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: Interested persons are invited to submit comments regarding the proposed information collection to Elena Walls, USAID, Bureau of Economic Growth, Education and Environment (E3)/Office of Education at *ewalls@usaid.gov.*

FOR FURTHER INFORMATION CONTACT: Elena Walls, USAID, Bureau of Economic Growth, Education and Environment (E3)/Office of Education at *ewalls@usaid.gov* or 202–468–3810.

SUPPLEMENTARY INFORMATION:

I. Abstract

While the field of international education has made great strides in recent years with raising the number and the quality of impact evaluations, their results are incomplete without cost data for these interventions. Policy makers and donors cannot make fully informed decisions about the best way to invest limited resources without information about the costs of achieving desired outputs and outcomes through different interventions or delivery strategies. Evidence on the cost of interventions is also critical for making responsible decisions about scaling and sustaining programs within country systems. The USAID Office of Education is working to address this gap through systematic efforts to measure costs of USAID interventions. The proposed form is intended to collect such data. The form includes a section for collecting data on the amount and details of contributions of partner governments and non-governmental entities (private companies, NGOs, individuals) toward achieving objectives of USAID-funded education activities, and a section on collecting information on details of interventions. ''Intervention'' is defined as a discreet set of tasks performed by the USAID awardee that is expected to lead to specific education-related outcomes. The ''contributions'' are in-kind or monetary donations by the host government or non-governmental entity valued at or over $1,000 and essential to achieving activity objectives. ''Dosage'' refers to the amount of intervention a beneficiary receives. The data will be collected by USAID/Missions from USAID implementing partners using worksheets in the form which will be adjusted according to the scope of work of the USAID-funded activity. Implementing partners will be submitting data in a spreadsheet file. USAID/Washington and USAID/Missions will use the data collected through this form used alongside expenditure data in cost analyses of education activities to calculate cost-efficiency and cost-effectiveness of USAID-funded education interventions. The main purpose is to enable a transfer of effective education interventions to host governments. The secondary purpose is to improve future planning and budgeting by USAID Missions. These objectives are aligned with Congressional requirements under Foreign Aid Transparency and Accountability Act of 2016 and under Reinforcing Education Accountability in Development Act or the READ Act of 2018. They are also closely aligned with the Journey to Self-Reliance for countries where USAID operates.

Method of Collection

Electronic.

II. Data

Title: USAID Education Cost Reporting Form.

OMB Number: Not assigned, new information collection.

Expiration Date: Not yet known.

Type of Request: New collection.

Affected Public: US and foreign-based organizations receiving funding for education programming from USAID.

Estimated Number of Respondents per Year: 90.

Estimated Total Annual Burden Hours per Respondent: Between 2 and 14 hours per respondent per year, average 8 hours.

III. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the sustaining USAID-funded programming beyond USAID funding; (2) the accuracy of USAID's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents. Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. The comments will also become a matter of public record.

Benjamin Sylla,

Evidence Team Lead, Engagement, Policy and Planning Division, Office of Education, U.S. Agency for International Development.

[FR Doc. 2019–15228 Filed 7–17–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Solicitation of Applications for Inviting Applications for the Rural Economic Development Loan and Grant Programs for Fiscal Year 2020

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This notice is to invite applications for loans and grants under the Rural Economic Development Loan and Grant (REDLG) Programs for fiscal year (FY) 2020, subject to the availability of funding. This notice is being issued in order to allow applicants sufficient time to leverage financing, prepare and submit their applications, and give the Agency time to process applications within FY 2020. Successful applications will be selected by the Agency for funding and subsequently awarded to the extent that funding may ultimately be made available through appropriations. An announcement on the website at *https://www.rd.usda.gov/newsroom/fy2020-appropriated-funding* will identify the amount received in the appropriations.

All applicants are responsible for any expenses incurred in developing their applications.

DATES: The deadline for completed applications to be received in the USDA Rural Development State Office no later than 4:30 p.m. (local time) are: First Quarter, September 30, 2019; Second Quarter, December 31, 2019; Third Quarter, March 31, 2020 and Fourth Quarter, June 30, 2020.

ADDRESSES: Applications must be submitted to the USDA Rural Development State Office for the State where the Project is located. A list of the USDA Rural Development State Office contacts can be found at: *http://www.rd.usda.gov/contact-us/state-offices.*

FOR FURTHER INFORMATION CONTACT: The Rural Development office for the state in which the applicant is located. A list of Rural Development State Office contacts is provided at the following link: *http://www.rd.usda.gov/contact-us/state-offices.*

SUPPLEMENTARY INFORMATION: The Agency encourages applications that will support recommendations made in the Rural Prosperity Task Force report to help improve life in rural America, *www.usda.gov/ruralprosperity.* Applicants are encouraged to consider projects that provide measurable results in helping rural communities build robust and sustainable economies through strategic investments in infrastructure, partnerships, and innovation. Key strategies include:

- Achieving e-Connectivity for Rural America
- Developing the Rural Economy
- Harnessing Technological Innovation
- Supporting a Rural Workforce
- Improving Quality of Life

Overview

Solicitation Opportunity Type: Rural Economic Development Loans and Grants.

Announcement Type: Initial Solicitation Announcement.

Catalog of Federal Domestic Assistance Number: 10.854.

Dates: The deadline for completed applications to be received in the USDA Rural Development State Office no later than 4:30 p.m. (local time) are: First Quarter, September 30, 2019; Second Quarter, December 31, 2019; Third Quarter, March 31, 2020 and Fourth Quarter, June 30, 2020.

A. Program Description

1. *Purpose of the Program.* The purpose of the program is to promote rural economic development and job creation projects.

2. *Statutory Authority.* These Programs are authorized under 7 U.S.C. 940c and 7 CFR part 4280, subpart A. Assistance provided to Rural areas, as defined, under this program may include business startup costs, business expansion, business incubators, Technical assistance feasibility studies, Advanced telecommunications services and computer networks for medical, educational, and job training services, and Community Facilities Projects for economic development.

Awards under the REDLG Programs will be made on a competitive basis using specific selection criteria contained in 7 CFR part 4280, subpart A. Information required to be in the application package includes Standard Form (SF) 424, ''Application for Federal Assistance;'' a Resolution of the Board of Directors; AD–1047, ''Debarment/Suspension Certification;'' AD–1049 ''Certification Regarding Drug-Free Workplace Requirements;'' SF LLL, Restrictions on Lobbying; RD 400–1, ''Equal Opportunity Agreement;'' RD 400–4, ''Assurance Agreement;'' Assurance Statement for the Uniform Act; Seismic Certification (if construction); and paperwork required in accordance with 7 CFR part 1970, ''Environmental Policies and Procedures.'' If the proposal involves new construction; large increases in employment; hazardous waste; a change in use, size, capacity, purpose, or location from an original facility; or is publicly controversial, the following is required: Environmental documentation in accordance with 7 CFR part 1970;'' RUS Form 7, ''Financial and Statistical Report;'' RUS Form 7a, ''Investments, Loan Guarantees, and Loans,'' or similar information; and written narrative of Project description. Applications will be tentatively scored by the State Offices and submitted to the National Office for review.

3. *Definition of Terms.* The definitions applicable to this notice are published at 7 CFR 4280.3.

4. *Application Awards.* The Agency will review, evaluate, and score applications received in response to this notice based on the provisions found in 7 CFR part 4280, subpart A, and as indicated in this notice. However, the Agency advises all interested parties that the applicant bears the burden in preparing and submitting an application in response to this notice whether or not funding is appropriated for these Programs in FY 2020.

B. Federal Award Information

Type of Awards: Loans and Grants.

Fiscal Year Funds: FY 2020.

Available Funds: Anyone interested in submitting an application for funding under these Programs are encouraged to consult the Rural Development Notices of Solicitation of Applications website at *http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas.*

Maximum Award: The Agency anticipates the following maximum amounts per award: Loans—$2,000,000; Grants—$300,000.

Award Dates: First Quarter, November 30, 2019; Second Quarter, February 28, 2020; Third Quarter, May 31, 2020; and Fourth Quarter, August 31, 2020.

Performance Period: October 1, 2020, through September 30, 2021.

Renewal or Supplemental Awards: None.

C. Eligibility Information

1. Eligible Applicants

Loans and grants may be made to any entity that is identified by USDA Rural Development as an eligible borrower under the Rural Electrification Act of 1936, as amended (Act). In accordance with 7 CFR 4280.13, applicants that are not delinquent on any Federal debt or otherwise disqualified from participation in these Programs are eligible to apply. An applicant must be eligible under 7 U.S.C. 940c. Notwithstanding any other provision of law, any former Rural Utilities Service borrower that has repaid or prepaid an

insured, direct, or guaranteed loan under the Act, or any not-for-profit utility that is eligible to receive an insured or direct loan under such Act shall be eligible for assistance under section 313(b)(2)(B) of such Act in the same manner as a borrower under such Act. All other restrictions in this notice will apply.

The Agency requires the following information to make an eligibility determination. These applications must include, but are not limited to, the following:

(a) An original and one copy of SF 424, ''Application for Federal Assistance (for non-construction);''

(b) Copies of applicant's organizational documents showing the applicant's legal existence and authority to perform the activities under the Grant;

(c) A proposed scope of work, including a description of the proposed Project, details of the proposed activities to be accomplished and timeframes for completion of each task, the number of months duration of the Project, and the estimated time it will take from grant approval to beginning of Project implementation;

(d) A written narrative that includes, at a minimum, the following items:

(i) An explanation of why the Project is needed, the benefits of the proposed Project, and how the Project meets the Grant eligible purposes;

(ii) Area to be served, identifying each governmental unit, *i.e.,* tribe, town, county, etc., to be affected by the Project;

(iii) Description of how the Project will coordinate economic development activities with other economic development activities within the Project area;

(iv) Businesses to be assisted, if appropriate, and economic development to be accomplished;

(v) An explanation of how the proposed Project will result in newly created, increased, or supported jobs in the area and the number of projected new and supported jobs within the next 3 years;

(vi) A description of the applicant's demonstrated capability and experience in providing the proposed Project assistance, including experience of key staff members and persons who will be providing the proposed Project activities and managing the Project;

(vii) The method and rationale used to select the areas and businesses that will receive the service;

(viii) A brief description of how the work will be performed, including whether organizational staff or consultants or contractors will be used; and

(ix) Other information the Agency may request to assist it in making a grant award determination.

(e) The last 3 years of financial information to show the applicant's financial capacity to carry out the proposed work. If the applicant is less than 3 years old, at a minimum, the information should include all balance sheet(s), income statement(s), and cash flow statement(s). A current audited report is required if available;

(f) Documentation regarding the availability and amount of other funds to be used in conjunction with the funds from REDLG; and

(g) A budget which includes salaries, fringe benefits, consultant costs, indirect costs, and other appropriate direct costs for the Project.

2. Cost Sharing or Matching

For loans, either the Ultimate Recipient or the Intermediary must provide supplemental funds for the Project equal to at least 20 percent of the loan to the Intermediary. For grants, the Intermediary must establish a Revolving Loan Fund (or Fund) and contribute an amount equal to at least 20 percent of the Grant. The supplemental contribution must come from Intermediary's funds which may not be from other Federal Grants, unless permitted by law.

3. Other

Applications will only be accepted for projects that promote rural economic development and job creation.

There are no ''responsiveness'' or ''threshold'' eligibility criteria for these loans and grants. There is no limit on the number of applications an applicant may submit under this announcement. In addition to the forms listed under the program description, Form AD 3030 ''Representations Regulation Felony Conviction and Tax Delinquent Status for Corporate Applicants,'' must be completed in the affirmative.

None of the funds made available by this or any other Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

None of the funds made available by this or any other Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

4. Completeness Eligibility

Applications will not be considered for funding if they do not provide sufficient information to determine eligibility or are missing required elements.

D. Application and Submission Information

1. Address To Request Application Package

For further information, entities wishing to apply for assistance should contact the USDA Rural Development State Office provided in the **ADDRESSES** section of this notice to obtain copies of the application package.

Prior to official submission of grant applications, applicants may request technical assistance or other application guidance from the Agency, as long as such requests are made at least 15 days prior to each quarter submission date. Technical assistance is not meant to be an analysis or assessment of the quality of the materials submitted, a substitute for agency review of completed applications, nor a determination of eligibility, if such determination requires in-depth analysis. The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

Applications must be submitted in paper format. Applications submitted to a Rural Development State Office must be received by the closing date and local time deadline.

All applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number which can be

obtained at no cost via a toll-free request line at (866) 705–5711 or at *http://fedgov.dnb.com/webform.* Each applicant applying for grant funds (unless the applicant is an individual or Federal awarding agency that is excepted from the requirements under 2 CFR 25.110(b) or (c) or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to: (i) Be registered in the System for Award Management (SAM) before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. The Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

Please note that applicants must locate the downloadable application package for this program by the Catalog of Federal Domestic Assistance Number or FedGrants Funding Opportunity Number, which can be found at *http://www.grants.gov.*

2. Content and Form of Application Submission

An application must contain all of the required elements. Each selection priority criterion outlined in 7 CFR 4280.42(b) must be addressed in the application. Failure to address any of the criterion will result in a zero-point score for that criterion and will impact the overall evaluation of the application. Copies of 7 CFR part 4280, subpart A, will be provided to any interested applicant making a request to a Rural Development State Office. An original copy of the application must be filed with the Rural Development State Office for the State where the Intermediary is located.

The applicant documentation and forms needed for a complete application are located in the Program Description section of this notice, and 7 CFR part 4280, subpart A. There are no specific formats required per this notice, and applicants may request forms and addresses from the **ADDRESSES** section of this notice.

(a) There are no specific limitations on the number of pages or other formatting requirements other than those described in the ''Program Description'' section.

(b) There are no specific limitations on the number of pages, font size and type face, margins, paper size, number of copies, and the sequence or assembly requirements.

(c) The component pieces of this application should contain original signatures on the original application.

3. Submission Dates and Times

(a) *Application Deadline Dates:* No later than 4:30 p.m. (local time) on: First Quarter, September 30, 2019; Second Quarter, December 31, 2019; Third Quarter, March 31, 2020; and Fourth Quarter, June 30, 2020.

Explanation of Dates: Applications must be in the USDA Rural Development State Office by the dates and times as indicated above. If the due date falls on a Saturday, Sunday, or Federal holiday, the application is due the next business day.

(b) The deadline date means that the completed application package must be received in the USDA Rural Development State Office by the deadline date and time established above. All application documents identified in this notice are required.

(c) If completed applications are not received by the deadline established above, the application will neither be reviewed nor considered under any circumstances. (d) The Agency will determine the application receipt date based on the actual date postmarked.

(e) If the grantee has a previously approved indirect cost rate, it is permissible, otherwise, the applicant may elect to charge the 10 percent indirect cost permitted under 2 CFR 200.414(f). Due to the time required to evaluate Indirect Cost Rates, it is likely that all funds will be awarded by the time the Indirect Cost Rate is determined. No foreign travel is permitted. Pre-Federal award costs will only be permitted with prior written approval by the Agency.

(f) Applicants must submit applications in hard copy format as previously indicated in the Application and Submission Information section of this notice. If the applicant wishes to hand deliver its application, the addresses for these deliveries can be located in the **ADDRESSES** section of this notice.

(g) If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

E. Application Review Information

1. Criteria

All eligible and complete applications will be evaluated and scored based on the selection criteria and weights contained in 7 CFR part 4280, subpart A. Failure to address any one of the criteria by the application deadline will result in the application being determined ineligible, and the application will not be considered for funding.

2. Review and Selection Process

The State Offices will review applications to determine if they are eligible for assistance based on requirements contained in 7 CFR part 4280, subpart A. If determined eligible, your application will be submitted to the National Office. Funding of projects is subject to the Intermediary's satisfactory submission of the additional items required by that subpart and the USDA Rural Development Letter of Conditions. The Agency reserves the right to award additional discretionary points under 7 CFR 4280.43.

In order to distribute funds among the greatest number of projects possible, applications will be reviewed, prioritized, and funded by ranking each State's highest scoring Project in highest to lowest score order. The highest scoring Project from each State will be considered that State's Priority One Project. Priority One projects will be ranked according to score from highest to lowest. The second highest scoring Project from each State will be considered the State's Priority Two Project. Priority Two projects will be ranked according to score from highest to lowest and so forth until all projects have been scored and ranked in priority order. All Priority One projects will be funded before any Priority Two projects and so forth until funds are depleted, so as to ensure broad geographic distribution of funding.

F. Federal Award Administration Information

1. *Federal Award Notices.* Successful applicants will receive notification for funding from the Rural Development State Office. Applicants must comply with all applicable statutes and regulations before the loan/grant award can be approved. Provided the application and eligibility requirements have not changed, an application not selected will be reconsidered in three subsequent quarterly funding competitions for a total of four competitions. If an application is withdrawn, it can be resubmitted and will be evaluated as a new application.

2. *Administrative and National Policy Requirements.* Additional requirements that apply to intermediaries or grantees selected for these Programs can be found in 7 CFR part 4280, subpart A. Awards are subject to USDA grant regulations at 2 CFR Chapter IV which incorporated the Office of Management and Budget (OMB) regulations 2 CFR 200.

All successful applicants will be notified by letter which will include a Letter of Conditions, and a Letter of Intent to Meet Conditions. This letter is not an authorization to begin performance. If the applicant wishes to consider beginning performance prior to the loan or grant being officially closed, all pre-award costs must be approved in writing and in advance by the Agency. The loan or grant will be considered officially awarded when all conditions in the Letter of Conditions have been met and the Agency obligates the funding for the Project.

Additional requirements that apply to intermediaries or grantees selected for these Programs can be found in 7 CFR 4280, subpart A; the Grants and Agreements regulations of the U.S. Department of Agriculture codified in 2 CFR 400.1to 400.2 and 2 CFR part 415 to 422, and successor regulations to these parts.

In addition, all recipients of Federal financial assistance are required to report information about first-tier sub-awards and executive compensation (see 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) reporting requirements (see 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)).

The following additional requirements apply to intermediaries or grantees selected for these Programs:

(a) Form RD 4280–2 ''Rural Business-Cooperative Service Financial Assistance Agreement.''

(b) Letter of Conditions.

(c) Form RD 1940–1, ''Request for Obligation of Funds.''

(d) Form RD 1942–46, ''Letter of Intent to Meet Conditions.''

(e) Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters-Primary Covered Transactions.''

(f) Form AD–1048 ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions.''

(g) Form AD–1049, ''Certification Regarding a Drug-Free Workplace Requirement (Grants).''

(h) Form AD–3031, ''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.'' Must be signed by corporate applicants who receive an award under this notice.

(i) Form RD 400–4, ''Assurance Agreement.'' Each prospective recipient must sign Form RD 400–4, ''Assurance Agreement,'' which assures USDA that the recipient is in compliance with Title VI of the Civil Rights Act of 1964, 7 CFR part 15, and other Agency regulations. That no person will be discriminated against based on race, color, or national origin, in regard to any program or activity for which the recipient receives Federal financial assistance. That nondiscrimination statements are in advertisements and brochures.

Collect and maintain data provided by Ultimate Recipients on race, sex, and national origin and ensure Ultimate Recipients collect and maintain this data. Race and ethnicity data will be collected in accordance with OMB **Federal Register** notice, ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity'' (62 FR 58782), October 30, 1997. Sex data will be collected in accordance with Title IX of the Education Amendments of 1972. These items should not be submitted with the application but should be available upon request by the Agency.

The applicant and the Ultimate Recipient must comply with Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, Age Discrimination Act of 1975, Executive Order 12250, Executive Order 13166 Limited English Proficiency (LEP), and 7 CFR part 1901, subpart E.

(j) SF LLL, ''Disclosure of Lobbying Activities,'' if applicable.

(k) Use Form SF 270, ''Request for Advance or Reimbursement.''

3. Reporting

(a) A Financial Status Report and a Project performance activity report will be required of all grantees on a quarterly basis until initial funds are expended and yearly thereafter, if applicable, based on the Federal fiscal year. The grantee will complete the Project within the total time available to it in accordance with the Scope of Work and any necessary modifications thereof prepared by the grantee and approved by the Agency. A final Project performance report will be required with the final Financial Status Report. The final report may serve as the last quarterly report. The final report must provide complete information regarding the jobs created and supported as a result of the Grant if applicable. Grantees must continuously monitor performance to ensure that time schedules are being met, projected work by time periods is being accomplished, and other performance objectives are being achieved. Grantees must submit an original of each report to the Agency no later than 30 days after the end of the quarter. The Project performance reports must include, but not be limited to, the following:

(1) A comparison of actual accomplishments to the objectives established for that period;

(2) Problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall Project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular Project work elements during established time periods. This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation; and

(3) Objectives and timetable established for the next reporting period.

(4) Any special reporting requirements, such as jobs supported and created, businesses assisted, or economic development which results in improvements in median household incomes, and any other specific requirements, should be placed in the reporting section of the Letter of Conditions.

(5) Within 90 days after the conclusion of the Project, the Intermediary will provide a final Project evaluation report. The last quarterly payment will be withheld until the final report is received and approved by the Agency. Even though the Intermediary may request reimbursement on a monthly basis, the last 3 months of reimbursements will be withheld until a final report, Project performance, and financial status report are received and approved by the Agency.

(b) In addition to any reports required by 2 CFR part 200 and 2 CFR 400.1 to 400.2 and 2 CFR part 415 to 422, the Intermediary or grantee must provide reports as required by 7 CFR part 4280, subpart A.

G. Federal Awarding Agency Contact(s)

For general questions about this announcement, please contact your USDA Rural Development State Office provided in the **ADDRESSES** section of this notice.

H. Civil Rights Requirements

All grants made under this notice are subject to Title VI of the Civil Rights Act

of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973, Title VIII of the Civil Rights Act of 1968, Title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

I. Other Information

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirement contained in this notice is approved by OMB under OMB Control Number 0570–0070.

Federal Funding Accountability and Transparency Act

All applicants, in accordance with 2 CFR part 25, must have a DUNS number, which can be obtained at no cost via a toll-free request line at (866) 705–5711 or online at *http://fedgov.dnb.com/webform.* Similarly, all applicants applying for grant funds must be registered in SAM prior to submitting an application. Applicants may register for the SAM at *http://www.sam.gov/SAM.* All recipients of Federal financial grant assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170.

Nondiscrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its agencies, offices, and employees, and institutions participating in or administering USDA Programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Bette B. Brand,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2019–15263 Filed 7–17–19; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–008]

Certain Circular Welded Carbon Steel Pipes and Tubes From Taiwan: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that exporters of certain circular welded carbon steel pipe and tubes from Taiwan sold subject merchandise in the United States at prices below normal value during the period of review (POR) May 1, 2017 through April 30, 2018. We invite all interested parties to comment on these preliminary results.

DATES: Applicable July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Rachel Greenberg, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0652.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on certain circular welded carbon steel pipes and tubes from Taiwan in accordance with section 751(a)(1)(B) of Tariff Act of 1930, as amended (the Act).[1] On July 12, 2018, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order* covering 20 companies.[2] On July 24, 2018, Commerce selected one producer/exporter of subject merchandise, Shin Yang Steel Co., Ltd. (Shin Yang), as the sole mandatory respondent for this review.[3]

On December 6, 2018, Commerce exercised its discretion to extend the deadline for the preliminary results.[4] Additionally, Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019, resulting in a revised deadline of July 10, 2019.[5]

Scope of the *Order*

The products covered by the *Order* are certain circular welded carbon steel pipes and tubes. The products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7306.30.5025, 7306.30.5032, 7306.30.5040, and 7306.30.5055. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description of the scope of the *Order* remains dispositive. For a full description of the scope, *see* the Preliminary Decision Memorandum.[6]

[1] *See Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Antidumping Duty Order,* 49 FR at 19369 (May 7, 1984) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 32270 (July 12, 2018) (*Initiation Notice*).

[3] *See* Memorandum, ''Respondent Selection,'' dated October 2, 2018 (Respondent Selection Memorandum).

[4] *See* Memorandum, ''Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Extension of Deadline for Preliminary Results of Antidumping Administrative Review,'' dated December 6, 2018.

[5] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Administrative Review: Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan; 2017–2018'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Methodology

Commerce is conducting this review in accordance with section 751 of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary results, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Determination of No Shipments

From July 18, 2018 through July 26, 2018, Sheng Yu Steel Co., Ltd. (Sheng Yu), Tension Steel Industries Co., Ltd. (Tension Steel), Yieh Hsing Enterprise. Co., Ltd. (Yieh Hsing), and Pat & Jeff Enterprise Co. Ltd. (P&J) timely filed statements reporting that they each made no shipments of subject merchandise to the United States during the POR. Subsequently, we received information from the U.S. Customs and Border Protection (CBP) confirming the no-shipment claims from Sheng Yu, Tension Steel, Yieh Hsing, and P&J. Based on the foregoing, Commerce preliminarily determines that Sheng Yu, Tension Steel, Yieh Hsing, and P&J had no shipments during the POR. For additional information regarding this determination, *see* the Preliminary Decision Memorandum. Consistent with our practice, Commerce is not rescinding this administrative review with respect to Sheng Yu, Tension Steel, Yieh Hsing, and P&J at this time, but intends to complete the review and issue appropriate instructions to CBP based on the final results of this review.[7]

Preliminary Results of This Review

As a result of this review, we calculated a preliminary weighted-average dumping margin of 2.44 percent for Shin Yang for the POR. Therefore, in accordance with section 735(c)(5)(A) of the Act, we assigned this weighted-average dumping margin of 2.44 percent calculated for Shin Yang to the fifteen companies not selected for individual review in these preliminary results, as referenced below. We preliminarily determine that the following weighted-average dumping margins exist for the period of May 1, 2017 through April 30, 2018:

Exporter/producer	Weighted-average dumping margin (percent)
Shin Yang Steel Co., Ltd	2.44
Chung Hung Steel Corp	2.44
Far East Machinery Co., Ltd	2.44
Far East Machinery Group	2.44
Fine Blanking & Tool Co., Ltd	2.44
Hou Lih Co., Ltd	2.44
Kao Hsing Chang Iron & Steel Corp	2.44
Lang Hwang Corp	2.44
Locksure Inc	2.44
New Chance Products Co., Ltd	2.44
Pin Tai Metal Inc	2.44
Shang Jouch Industrial Co., Ltd	2.44
Shuan Hwa Industrial Co., Ltd	2.44
Titan Fastech Ltd	2.44
Yeong Shien Industrial Co., Ltd	2.44
Yousing Precision Industry Co., Ltd	2.44

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.

For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[8] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* If Shin Yang's weighted-average dumping margin is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review where applicable.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Shin Yang for which it did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. We intend to issue instructions to CBP 15 days after the publication date of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the *ad valorem* rate is *de minimis,* then the cash deposit rate will be zero); (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 9.70 percent, the all-others rate established in the investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

[7] *See e.g., Certain Frozen Warmwater Shrimp from Thailand: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306, 51307 (August 28, 2014).

[8] In these preliminary results, Commerce applied the assessment rate calculation methodology adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[9] *See Order.*

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed within ten days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments within 30 days of the publication of this nature, pursuant to 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[10] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Case and rebuttal briefs should be filed using ACCESS.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.[11] If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined.[12] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

The preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 10, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–15187 Filed 7–17–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–848]

Freshwater Crawfish Tail Meat From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain companies covered by the administrative review made sales of subject merchandise at prices below normal value. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Andre Gziryan at (202) 482–2201 (Hubei Qianjiang), Jacob Keller (202) 482–4849 (Nanjing Gemsen), AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on freshwater crawfish tail meat from the People's Republic of China (China). The period of review (POR) is September 1, 2017 through August 31, 2018. This administrative review covers two mandatory respondents, Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd. (Hubei Qianjiang) and Nanjing Gemsen International Co., Ltd. (Nanjing Gemsen). Commerce preliminarily determines that sales of subject merchandise by Hubei Qianjiang have not been made at prices below normal value, and sales of subject merchandise by Nanjing Gemsen have been made at prices below normal value.

Scope of the Order

The merchandise subject to the antidumping duty order is freshwater crawfish tail meat, which is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 1605.40.10.10, 1605.40.10.90, 0306.19.00.10, and 0306.29.00.00. On February 10, 2012, Commerce added HTSUS classification number 0306.29.01.00 to the scope description pursuant to a request by U.S. Customs and Border Protection (CBP). On September 21, 2018, Commerce added HTSUS classification numbers 0306.39.0000 and 0306.99.0000 to the scope description pursuant to a request by CBP. While the HTSUS numbers are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.[1]

Preliminary Determination of No Shipments

Five companies that received a separate rate in previous segments of the proceeding and are subject to this review reported that they did not have any exports of subject merchandise during the POR.[2] Additionally, Nanjing

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See* 19 CFR 351.310(c).

[12] *See* 19 CFR 351.310(c).

[1] *See* Memorandum, ''Freshwater Crawfish Tail Meat from the People's Republic of China: Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review; 2017–2018,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[2] *See* No-Shipment Letters from Weishan Hongda Aquatic Food Co., Ltd., dated November 30, 2018; Kunshan Xinrui Trading Co., Ltd. and Nanjing

Continued

Yinxiangchen International Trade Co., Ltd. is subject to the semi-annual new shipper review covering the period September 1, 2017 through February 28, 2018, and reported that it did not have exports of subject merchandise in the last six months of this administrative review (*i.e.,* March 1, 2018 through August 31, 2018).[3] We requested that CBP report any contrary information.[4] In response to our inquiry, CBP indicated that these six companies did not have any shipments of the subject merchandise sold to the United States during the POR.[5] Further, consistent with our practice, we find that it is not appropriate to rescind the review with respect to these companies but, rather, to complete the review and issue appropriate instructions to CBP based on the final results of review.[6]

Separate Rates

Commerce preliminarily determines that eight respondents are eligible to receive separate rates in this review.[7]

Separate Rate for Eligible Non-Selected Respondents

Commerce preliminarily determines that the respondents not selected for individual examination, Deyan Aquatic Products and Food Co., Ltd. (Deyan Aquatic); Hubei Nature Agriculture Industry Co., Ltd. (Hubei Nature); Hubei Yuesheng Aquatic Products Co., Ltd. (Hubei Yuesheng); Xiping Opeck Food Co., Ltd. (Xiping Opeck); Xuzhou Jinjiang Foodstuffs Co., Ltd. (Xuzhou Jinjiang); and Yancheng Hi-King Agricultural Developing Co., Ltd. (Yancheng Hi-King) are eligible to receive a separate rate in the administrative review.[8] Consistent with our practice, we assigned to Deyan Aquatic, Hubei Nature, Hubei Yuesheng, Xiping Opeck, Xuzhou Jinjiang, and Yancheng Hi-King the margin calculated for Nanjing Gemsen as the separate rate for the preliminary results of this review.[9]

China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[10] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review and the entity's rate is not subject to change (*i.e.,* 223.01 percent).[11] Aside from the no-shipments and separate rate companies discussed above, Commerce preliminarily determines that Jingzhou Tianhe Aquatic Products Co., Ltd., for which a review was requested (which did not file a separate rate application) is part of the China-wide entity.[12]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213. Export price is calculated in accordance with section 772(c) of the Act. Because China is a non-market economy within the meaning of section 771(18) of the Act, normal value has been calculated in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in Commerce's Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results

Commerce preliminarily determines that the following weighted-average dumping margins exist during the period September 1, 2017 through August 31, 2018:

Producer/exporter	Weighted-average margin (percent)
Deyan Aquatic Products and Food Co., Ltd	7.92
Hubei Nature Agriculture Industry Co., Ltd	7.92
Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd	0.00
Hubei Yuesheng Aquatic Products Co., Ltd	7.92
Nanjing Gemsen International Co., Ltd	7.92
Xiping Opeck Food Co., Ltd	7.92
Xuzhou Jinjiang Foodstuffs Co., Ltd	7.92
Yancheng Hi-King Agricultural Developing Co., Ltd	7.92

Disclosure

We intend to disclose calculations performed in these preliminary results to parties within five days after public announcement of the preliminary results.[13]

Public Comment

Pursuant to 19 CFR 351.309(c)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[14] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[15] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue;

Yinxiangchen International Trade Co., Ltd., each dated December 4, 2018; Shanghai Ocean Flavor International Trading Co., Ltd. and Anhui Luan Hongyuan Foodstuffs Co., Ltd., each dated December 14, 2018; and China Kingdom (Beijing) Import & Export Co., Ltd. (China Kingdom), dated February 28, 2019. China Kingdom submitted its no shipment letter past the 30-day deadline, however, we have accepted it as a clarification to its separate rate certification (*see* China Kingdom's Letter, ''Freshwater Crawfish Tail Meat from the People's Republic of China Separate Rate Certification,'' dated December 14, 2018 at 4 and 6) that it had sales to the United States but no suspended entries of subject merchandise into the United States during the POR.

[3] *See* Nanjing Yinxiangchen International Trade Co., Ltd.'s Letter, ''Freshwater Crawfish Tail Meat from the People's Republic of China: Concurrent Shipment Certification,'' dated December 4, 2018.

[4] *See* CBP message numbers 9150301, 9150302, 9150303, 9150304, 9157303, and 9157304, available at *https://aceservices.cbp.dhs.gov/adcvdweb.*

[5] *See* Memorandum, ''No shipment inquiry with respect to the companies below during the period 09/01/2017 through 08/31/2018,'' dated July 2, 2019.

[6] *See, e.g., Wooden Bedroom Furniture from the People's Republic of China: Final Results and Final Rescission, In Part, of Administrative Review and Final Results of New Shipper Review; 2013,* 80 FR 34619 (June 17, 2015).

[7] *See* Preliminary Decision Memorandum at 5–6.

[8] *Id.*at 7–8.

[9] *Id.*

[10] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[11] *See Freshwater Crawfish Tail Meat from the People's Republic of China; Notice of Final Results of Antidumping Duty Administrative Review,* 68 FR 19504 (April 21, 2003).

[12] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 57411 (November 15, 2018) (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.''); *see also* Preliminary Decision Memorandum at 8.

[13] *See* 19 CFR 351.224(b).

[14] *See* 19 CFR 351.309(c).

[15] *See* 19 CFR 351.309(d).

(2) a brief summary of the argument; and (3) a table of authorities.[16]

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[17] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Unless the deadline is extended, Commerce intends to issue the final results of this review, including the results of its analysis of issues raised by parties in their comments, within 120 days after the publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuing the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[18] If a respondent's weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent) in the final results of this review, we will calculate an importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and, where possible, the total entered value of sales. Specifically, Commerce will apply the assessment rate calculation method adopted in *Final Modification for Reviews.*[19] Where an importer- (or customer-) specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[20]

For entries that were not reported in the U.S. sales databases submitted by exporters individually examined during this review, Commerce will instruct CBP to liquidate such entries at the China-wide rate. If Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide rate.[21]

We intend to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review.

Cash Deposit Requirements

On June 7, 2019, as a result of the five-year (sunset) review, Commerce revoked the antidumping duty order on imports of freshwater crawfish tail meat from China.[22] In the *Revocation Notice,* Commerce stated that it intends to issue instructions to CBP to terminate the suspension of liquidation and to discontinue the collection of cash deposits on entries of subject merchandise, entered or withdrawn from warehouse, on or after May 16, 2019.[23] Furthermore, because the antidumping duty order on freshwater crawfish tail meat from China has been revoked as a result of the *Revocation Notice,* Commerce will not issue cash deposit instructions at the conclusion of this administrative review.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1), 751(a)(3), and 777(i) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: July 11, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–15191 Filed 7–17–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–832]

Pure Magnesium From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) continues to find that Tianjin Magnesium International, Co., Ltd. (TMI) and Tianjin Magnesium Metal Co., Ltd. (TMM) (collectively, TMI/TMM) had no shipments of subject merchandise covered by the antidumping duty order on pure magnesium from the People's Republic of China (China) for the period of review (POR) May 1, 2017 through April 31, 2018.

DATES: Applicable July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane or Brendan Quinn, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5449 or (202) 482–5848, respectively.

SUPPLEMENTARY INFORMATION:

[16] *See* 19 CFR 351.309(c)(2) and (d)(2); and 19 CFR 351.303 (for general filing requirements).

[17] *See* 19 CFR 351.310(c).

[18] *See* 19 CFR 351.212(b)(1).

[19] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8103 (February 14, 2012) (*Final Modification for Reviews*).

[20] *See* 19 CFR 351.106(c)(2).

[21] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65695 (October 24, 2011).

[22] *See Freshwater Crawfish Tail Meat from the People's Republic of China: Final Results of Sunset Review and Revocation of Antidumping Duty Order,* 84 FR 26647 (June 7, 2019) (*Revocation Notice*).

[23] *See Revocation Notice.*

Background

On March 13, 2019, Commerce published the *Preliminary Results.*[1] We invited interested parties to comment on the *Preliminary Results,* but no comments were received. Accordingly, we made no changes to the *Preliminary Results.*

Commerce conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019. Accordingly, the revised deadline for the issuance of these final results is now July 12, 2019.[2]

Scope of the Order

The product covered by this antidumping duty order is pure magnesium from China, regardless of chemistry, form or size, unless expressly excluded from the scope of the order. Pure magnesium is a metal or alloy containing by weight primarily the element magnesium and produced by decomposing raw materials into magnesium metal. Pure primary magnesium is used primarily as a chemical in the aluminum alloying, desulfurization, and chemical reduction industries. In addition, pure magnesium is used as an input in producing magnesium alloy. Pure magnesium encompasses products (including, but not limited to, butt ends, stubs, crowns and crystals) with the following primary magnesium contents:

(1) Products that contain at least 99.95% primary magnesium, by weight (generally referred to as ''ultra pure'' magnesium); Magnesium Alloy''[3] and are thus outside the scope of the existing antidumping orders on magnesium from China (generally referred to as ''alloy'' magnesium).

(2) Products that contain less than 99.95% but not less than 99.8% primary magnesium, by weight (generally referred to as ''pure'' magnesium); and

(3) Products that contain 50% or greater, but less than 99.8% primary magnesium, by weight, and that do not conform to ASTM specifications for alloy magnesium (generally referred to as ''off-pecification pure'' magnesium).

''Off-specification pure'' magnesium is pure primary magnesium containing magnesium scrap, secondary magnesium, oxidized magnesium or impurities (whether or not intentionally added) that cause the primary magnesium content to fall below 99.8% by weight. It generally does not contain, individually or in combination, 1.5% or more, by weight, of the following alloying elements: Aluminum, manganese, zinc, silicon, thorium, zirconium and rare earths.

Excluded from the scope of the order are alloy primary magnesium (that meets specifications for alloy magnesium), primary magnesium anodes, granular primary magnesium (including turnings, chips and powder) having a maximum physical dimension (*i.e.,* length or diameter) of one inch or less, secondary magnesium (which has pure primary magnesium content of less than 50% by weight), and remelted magnesium whose pure primary magnesium content is less than 50% by weight.

Pure magnesium products covered by the order are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 8104.11.00, 8104.19.00, 8104.20.00, 8104.30.00, 8104.90.00, 3824.90.11, 3824.90.19 and 9817.00.90. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that TMI/TMM[4] had no shipments of the subject merchandise, and, therefore, no reviewable transactions, during the POR.[5] As we have not received any information to contradict our preliminary finding, we determine that TMI/TMM did not have any shipments of subject merchandise during the POR and intend to issue appropriate instructions that are consistent with our automatic assessment clarification for these final results.[6]

Assessment Rates

Commerce determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review.

Additionally, consistent with Commerce's refinement to its assessment practice in non-market economy cases, for TMI/TMM, exporters under review, which we determined had no shipments of the subject merchandise during the POR, any suspended entries of subject merchandise from TMI/TMM will be liquidated at the China-wide rate.[7]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of these final results of administrative review for shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For TMI/TMM, which claimed no shipments, the cash deposit rate will remain unchanged from the rate assigned to TMI/TMM in the most recently completed review of the company; (2) for previously investigated or reviewed Chinese and non-Chinese exporters who are not under review in this segment of the proceeding but who have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the China-wide rate of 111.73 percent;[8] and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-PRC

[1] *See Pure Magnesium from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018,* 84 FR 9091 (March 13, 2019) (*Preliminary Results*).

[2] *See* memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[3] The meaning of this term is the same as that used by the American Society for Testing and Materials in its Annual Book for ASTM Standards: Volume 01.02 Aluminum and Magnesium Alloys.

[4] In the 2011–2012 administrative review of the order, Commerce determined TMM and TMI to be collapsed and treated as a single entity for purposes of that proceeding. *See Pure Magnesium from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2011–2012,* 79 FR 94 (January 2, 2014) and accompanying Issues and Decision Memorandum at Comment 5. Because there have been no changes to the facts supporting the original collapsing determination, which remains unchallenged in this review, we continue to find that these companies are part of a single entity for the purposes of this administrative review.

[5] *See Preliminary Results,* 84 FR at 9092.

[6] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) (*Assessment Notice*); *see also* ''Assessment Rates'' section below.

[7] For a full discussion of this practice, *see Assessment Notice.*

[8] *See Pure Magnesium from the People's Republic of China: Final Results of the 2008–2009 Antidumping Duty Administrative Review of the Antidumping Duty Order,* 75 FR 80791 (December 23, 2010).

exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results and this notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: July 2, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–15188 Filed 7–17–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–810]

Polyethylene Terephthalate Resin From the Sultanate of Oman: Preliminary Results of Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that OCTAL SAOC–FZC (OCTAL) did not make sales of subject merchandise at less than normal value during the period of review (POR) May 1, 2017 through April 30, 2018. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2018, Commerce notified interested parties of the opportunity to request an administrative review of the antidumping duty (AD) order on polyethylene terephthalate resin (PET resin) from the Sultanate of Oman (Oman).[1] Commerce received timely requests from DAK Americas, LLC, Indorama Ventures USA, Inc., and Nan Ya Plastics Corporation, America (collectively, the petitioners), and OCTAL to conduct an administrative review of OCTAL during the POR.[2] On July 12, 2018, Commerce published a notice initiating an AD administrative review of PET resin from Oman covering OCTAL for the POR.[3] OCTAL and the petitioners filed numerous submissions in this review which are discussed in the accompanying Preliminary Decision Memorandum.[4]

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018 through the resumption of operations on January 29, 2019.[5] If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. Based on tolling, the revised deadline for the preliminary results was March 12, 2019. However, on March 4, 2019, Commerce extended the deadline for issuing the preliminary results of this review. The current deadline for issuing the preliminary results of review is July 10, 2019.

Scope of the Order

The merchandise covered by this order is PET resin having an intrinsic viscosity of at least 0.70, but not more than 0.88, deciliters per gram. The merchandise subject to this order is properly classified under subheadings 3907.60.00.30, 3907.61.0000, 3907.61.0010, 3907.61.0050, 3907.69.0000, 3907.69.0010, and 3907.69.0050 of the Harmonized Tariff Schedule of the United States (HTSUS).[6] Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by this order is dispositive. For a full description of the scope of the order, *see* Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price have been calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed Preliminary Decision

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 19047 (May 1, 2018).

[2] *See* Petitioners' Request for Review dated May 31, 2018; *see also* OCTAL's Request for Review dated May 31, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 32270 (July 12, 2018).

[4] For a full discussion of the background, *see* Memorandum, ''Decision Memorandum for Preliminary Results of the 2017–2018 Antidumping Duty Administrative Review of Polyethylene Terephthalate Resin from the Sultanate of Oman,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[6] On January 27, 2017, Commerce added HTS numbers 3907.61.0000 and 3907.69.0000 to the Case Reference File. *See* Commerce Memorandum re: ''Request from Customs and Border Protection to Update the ACE Case Reference File: Polyethylene Terephthalate Resin form the Sultanate of Oman (A–523–810) dated January 31, 2017. Further, on February 28, 2019, Commerce added HTS numbers 3907.61.0010, 3907.61.0050, 3907.69.0010 and 3907.69.0050 to the Case Reference File. *See* Commerce Memorandum re: ''Request from U.S. Customs and Border Protection to Update the ACE Case Reference File: Polyethylene Terephthalate Resin form the Sultanate of Oman (A–523–810) dated February 28, 2019.

Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period May 1, 2017 through April 30, 2018:

Manufacturer/exporter	Weighted-average margin (percent)
OCTAL SAOC–FZC ..	0.07 (*de minimis*).

Disclosure and Public Comment

Commerce intends to disclose the calculations used in our analysis to interested parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing case briefs.[7] Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each brief: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities.[8] Executive summaries should be limited to five pages total, including footnotes.[9] Case and rebuttal briefs should be filed using ACCESS.[10]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. If a hearing is requested, Commerce will notify interested parties of the hearing date and time. Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically *via* ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, unless otherwise extended.[11]

Assessment Rates

Upon issuance of the final results, Commerce will determine, and Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b)(1). We will calculate importer-specific assessment rates equal to the ratio of the total amount of dumping calculated for examined sales with a particular importer to the total entered value of the sales in accordance with 19 CFR 351.212(b)(1). Where the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future deposits of estimated duties, where applicable.

For entries of subject merchandise during the POR produced by the respondent for which it did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue instructions to CBP 15 days after the date of publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of PET resin from Oman entered, or withdrawn from warehouse, for consumption on or after the date of publication of the notice of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for OCTAL will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established in the most recently completed segment of the proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 7.62 percent *ad valorem,* the all-others rate established in the less-than-fair-value investigation.[12] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1).

Dated: July 10, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–15189 Filed 7–17–19; 8:45 am]

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[7] *See* 19 CFR 351.309(d)(1).

[8] *See* 19 CFR 351.309(c)(2) and (d)(2).

[9] *Id.*

[10] *See* 19 CFR 351.303.

[11] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

[12] *See Certain Polyethylene Terephthalate Resin from Canada, the People's Republic of China, India, and the Sultanate of Oman: Amended Final Affirmative Antidumping Determination (Sultanate of Oman) and Antidumping Duty Orders,* 81 FR 27979 (May 6, 2016).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501]

Circular Welded Carbon Steel Standard Pipe and Tube Products From Turkey: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that producers and/or exporters subject to this administrative review made sales of subject merchandise at less than normal value. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Magd Zalok or Karine Gziryan, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–4162 or 202–482–4081, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on welded carbon steel standard pipe and tube products (welded pipe and tube) from Turkey. The period of review (POR) is May 1, 2017 through April 30, 2018. Commerce published the notice of initiation of this administrative review on July 12, 2018.[1] The preliminary results are listed below in the section titled ''Preliminary Results of Review.''

This review covers the following companies: Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (Borusan Mannesmann) and Borusan Istikbal Ticaret T.A.S. (Borusan Istikbal) (collectively, Borusan);[2] Toscelik Profil ve Sac Endustrisi A.S., Tosyali Dis Ticaret A.S., and Toscelik Metal Ticaret A.S. (Toscelik Metal) (collectively, Toscelik);[3] Borusan Birlesik Boru Fabrikalari San ve Tic (Borusan Birlesik); Borusan Gemlik Boru Tesisleri A.S. (Borusan Gemlik); Borusan Holding (BMBYH), Borusan Ihracat Ithalat ve Dagitim A.S. (Borusan Ihracat); Borusan Ithicat ve Dagitim A.S. (Borusan Ithicat); Borusan Mannesmann Yatirim Holding (BMYH), Tubeco Pipe and Steel Corporation (Tubeco); Erbosan Erciyas Boru Sanayi ve Ticaret A.S. (Erbosan); Kale Baglanti Teknolojileri San. ve Tic. (Kale Baglanti), Noksel Selik Boru Sanayi A.S. (Noksel Selik), Yucel Boru ve Profil Endustrisi A.S. (Yucel), Yucelboru Ihracat Ithalat ve Pazarlama A.S. (Yucelboru), Cayirova Boru Sanayi ve Ticaret A.S. (Cayirova), and Cinar Boru Profil San. ve Tic. As (Cinar Boru). The mandatory respondents in this administrative review are Borusan and Toscelik.[4]

On January 28, 2019, Commerce exercised its discretion to toll all deadlines affected by the closure of the Federal Government from December 22, 2019 through January 28, 2019.[5] Based on the tolled deadline, the revised deadline for the preliminary results of this review became June 20, 2019. On February 21, 2019, we extended the deadline for the preliminary results to June 20, 2019.[6] On June 4, 2019, we further extended the deadline for the preliminary results, until July 10, 2019.[7]

For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[8]

Scope of the Order

The merchandise subject to the order is welded pipe and tube. The welded pipe and tube subject to the order is currently classifiable under subheading 7306.30.10.00, 7306.30.50.25, 7306.30.50.32, 7306.30.50.40, 7306.30.50.55, 7306.30.50.85, and 7306.30.50.90 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheading is provided for convenience and customs purposes. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of the topics included in the Preliminary Decision Memorandum is included in the Appendix to this notice. One of the issues raised in the course of this review was the treatment of duties paid pursuant to section 232 of the Trade Expansion Act of 1967, as amended.[9] As explained in the Preliminary Decision Memorandum, we have adjusted both export and constructed export prices to reflect the payment of those duties, in accordance with section 772(c)(2)(A) of the Act.[10]

In addition, the petitioner[11] has alleged the existence of a particular market situation in Turkey with respect to the price of the input, hot rolled coil,

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 32270, 32277 (July 12, 2018).

[2] In prior segments of this proceeding, we treated Borusan Mannesmann Boru Sanayi ve Ticaret A.S. and Borusan Istikbal Ticaret T.A.S. as a single entity. *See, e.g., Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2013–2014,* 80 FR 76674, 76674 n.2 (December 10, 2015) (*Welded Pipe and Tube from Turkey 2013–2014*). We preliminarily determine that there is no evidence on the record for altering our treatment of Borusan Mannesmann Boru Sanayi ve Ticaret A.S. and Borusan Istikbal Ticaret T.A.S. as a single entity. The record does not support treating the following companies as part of the Borusan Mannesmann Boru Sanayi ve Ticaret A.S./Borusan Istikbal Ticaret T.A.S. entity: (1) Borusan Birlesik; (2) Borusan Gemlik; (3) Borusan Ihracat; (4) Borusan Ithicat; and (5) Tubeco. Accordingly, as discussed *infra,* each of these five companies will be assigned the rate applicable to companies not selected for individual examination in this review.

[3] In prior segments of this proceeding, we treated Toscelik Profil ve Sac Endustrisi A.S., Tosyali Dis Ticaret A.S., and Toscelik Metal as a single company. *See, e.g.,* Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2013–2014, 80 FR 76674, 76674 n.2 (December 10, 2015). We preliminarily determine that there is no evidence on the record for altering our treatment of Toscelik Profil ve Sac Endustrisi A.S., Tosyali Dis Ticaret A.S., and Toscelik Metal as a single company.

[4] *See* Memorandum, ''Administrative Review of the Antidumping Duty Order on Circular Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Respondent Selection,'' dated August 8, 2018.

[5] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[6] *See* Memorandum, ''Certain Circular Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,'' dated February 21, 2019.

[7] *See* Memorandum, ''Certain Circular Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,'' dated June 4, 2019.

[8] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Circular Welded Carbon Steel Standard Pipe and Tube Products from Turkey; 2017–2018'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[9] *See* 19 U.S.C. 1862.

[10] *See* Preliminary Decision Memorandum at 11–16.

[11] The petitioner is the Wheatland Tube Company.

pursuant to section 773(e) of the Act.[12] We have preliminarily determined that a particular market situation exists and have made an upward adjustment to the costs of hot rolled coil both imported into Turkey and sourced in Turkey utilizing a regression analysis placed on the record by the petitioner.[13]

The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and to all parties in Commerce's Central Records Unit, located at room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/index.html.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Determination of No Shipments

On July 23, 2018, Erbosan submitted a letter to Commerce certifying that it had no sales, shipments, or entries of the subject merchandise to the United States during the POR.[14] Erbosan further certified that it did not know or have reason to know that any of its customers would subsequently export or sell Erbosan's merchandise to the United States during the POR. On July 25, 2018, Cayirova, Yucel, and Yucelboru submitted a letter to Commerce certifying that they each individually had no sales, shipments, or entries of the subject merchandise to the United State during the POR.[15] On August 13, 2018, Borusan Istikbal, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, Borusan Holding, BMBYH, and Tubeco submitted a letter to Commerce certifying that they each individually had no sales, shipments, or entries of the subject merchandise to the United States during the POR.[16] On April 25, 2018, consistent with our practice, we issued a ''No Shipment Inquiry'' to U.S. Customs and Border Protection (CBP) to confirm that there were no entries of welded pipe and tube from Turkey exported by Erbosan, Borusan Istikbal, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, Borusan Holding, BMBYH, Tubeco, Cayirova, Yucel, or Yucelboru during the POR.[17] We received no information from CBP regarding the existence of entries of subject merchandise from these companies during the POR. Based on their certifications and our analysis of CBP information, we preliminarily determine that Erbosan, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, Borusan Holding, BMBYH, Tubeco, Cayirova, Yucel, and Yucelboru each had no reviewable transactions during the POR. Consistent with our practice, we are not preliminarily rescinding the review with respect to these eleven companies, but, rather, we will complete the review for these companies and issue appropriate instructions to CBP based on the final results of this review.[18]

Further, as noted above, Borusan Istikbal also submitted a no-shipment certification on August 13, 2018. However, we continue to find Borusan Istikbal to be part of the single entity, Borusan, and we find no record evidence that warrants altering this treatment. Therefore, because we find that Borusan had shipments during this POR, we have not made a preliminary determination of no-shipments with respect to Borusan Istikbal. Furthermore, three companies, Kale Baglanti, Noksel Selik, and Cinar Boru, remain subject to this administrative review because none of these three companies: (1) Was selected as a mandatory respondent;[19] (2) was the subject of a withdrawal of request for review; (3) requested to participate as a voluntary respondent; or (4) submitted a claim of no shipments. As such, these three companies remain as unexamined respondents.

Preliminary Results of Review

As a result of this review, we calculated a weighted-average dumping margin of 14.73 percent for Borusan and a *de minimis* margin for Toscelik for the period May 1, 2017 through April 30, 2018. We assigned the three non-selected companies the all-others rate in these preliminary results, as referenced below:

Producer or exporter	Weighted-average dumping margin (percent)
Borusan Mannesmann Boru Sanayi ve Ticaret A.S./Borusan Istikbal Ticaret T.A.S	14.73
Toscelik Profil ve Sac Endustrisi A.S./Tosyali Dis Ticaret A.S./Toscelik Metal Ticaret A.S	0.00
Kale Baglanti Teknolojileri San. ve Tic	14.74
Noksel Selik Boru Sanayi A.S	14.74
Cinar Boru Profil San. ve Tic. As	14.74

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b)(1). We intend to issue instructions to CBP 15 days after the date of publication of the final results of this review.

If either Borusan's or Toscelik's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1). Where either a respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

With respect to Erbosan, Borusan Birlesik, Borusan Gemlik, Borusan Ihracat, Borusan Ithicat, Borusan Holding, BMBYH, Tubeco, Cayirova, Yucel, and Yucelboru, if we continue to find that these companies had no shipments of subject merchandise in the final results, we will instruct CBP to liquidate any existing entries of merchandise produced by these companies, but exported by other

[12] *See* Petitioner's Letter, ''Circular Welded Carbon Steel Standard Pipe and Tube Products from Turkey: Particular Market Situation Allegation,'' dated January 29, 2019.

[13] *See* Preliminary Decision Memorandum at 24–25.

[14] *See* Letter from Borusan, ''No Shipment Certification of Erbosan Erciyas Boru Sanayi ve Ticaret A.S. in the 2017–2018 Administrative Review of the Antidumping Duty Order Involving Certain Welded Carbon Steel Standard Pipe from Turkey,'' dated July 23, 2018.

[15] *See* Letter from Cayirova, Yucel, and Yucelboru, ''Circular Welded Carbon Steel Pipes and Tubes from Turkey; Notification of No Shipments,'' dated July 25, 2018.

[16] *See* Letter from Borusan Istikbal, Borusan Birlesik, Borusan Gemlik, Borusan Iharcat, Borusan Ithicat, and Tubeco, ''Circular Welded Carbon Steel Pipes and Tubes from Turkey, Case No. A–489–501: No Shipment Letter,'' dated August 13, 2018.

[17] *See* CBP message number 8115302, dated April 25, 2018.

[18] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011); and the ''Assessment Rates'' section, below; *see also Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306, 51307 (August 28, 2014).

[19] *See* Respondent Selection Memorandum.

parties, at the rate for the intermediate reseller, if available, or at the all-others rate.[20] In this review, we have preliminarily calculated a weighted-average dumping margin of 14.73 percent for Borusan. In addition, we have preliminarily calculated a *de minimis* margin for Toscelik, the other mandatory respondent. When only one weighted-average dumping margin for the individually investigated respondent is not zero, *de minimis,* or based entirely on facts available, the rate for companies that we did not examine will be equal to that single weighted-average dumping margin. Accordingly, we have preliminarily assigned to Kale Baglanti, Noksel Selik, and Cinar Boru, companies not individually examined in this review, a margin of 14.74 percent, which is the all-others rate established in the less-than-fair-value investigation.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of welded pipe and tube from Turkey entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 14.74 percent *ad valorem,* the all-others rate established in the less-than-fair-value investigation.[21] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose the calculations used in our analysis to interested parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing case briefs.[22] Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each brief: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities.[23] Executive summaries should be limited to five pages total, including footnotes.[24] Case and rebuttal briefs should be filed using ACCESS.[25]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. If a hearing is requested, Commerce will notify interested parties of the hearing schedule. Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, unless otherwise extended.[26]

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 10, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–15193 Filed 7–17–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR009

Taking of Marine Mammals Incidental to Specific Activities; Taking of Marine Mammals Incidental To Pile Driving Activities During Construction of a Ferry Terminal at Seaplane Lagoon, Alameda Point, San Francisco, California

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

[20] *See, e.g., Magnesium Metal from the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal from the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010).

[21] *See Antidumping Duty Order; Welded Carbon Steel Standard Pipe and Tube Products from Turkey,* 51 FR 17784 (May 15, 1986).

[22] *See* 19 CFR 351.309(d)(1).

[23] *See* 19 CFR 351.309(c)(2) and (d)(2).

[24] *Id.*

[25] *See* 19 CFR 351.303.

[26] *See* section 751(a)(3)(A) of the Act.

SUMMARY: NMFS has received a request from the City of Alameda (City) for authorization to take marine mammals incidental to pile driving activities during construction of a ferry terminal at Seaplane Lagoon, Alameda Point, San Francisco, California. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in *Request for Public Comments* at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than August 19, 2019.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Egger@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Stephanie Egger, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On February 22, 2019, NMFS received a request from the City for an IHA to take marine mammals incidental to pile driving activities during construction of a ferry terminal in Seaplane Lagoon, Alameda, California. The application was deemed adequate and complete on June 28, 2019. The applicant's request is for take seven species of marine mammals by Level B harassment only. Neither the City nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

The purpose of this project is to provide facilities to expand the existing ferry service from Alameda and Oakland to San Francisco in order to address the limited capacity at the existing Main Street Ferry Terminal, accommodate the anticipated increase in demand for ferry service from Alameda to San Francisco due to planned development of the Alameda Point Project, and to provide enhanced emergency response services to Alameda in the event of transbay service disruptions.

Currently, the nearest operational ferry terminal to Alameda Point is the Alameda Main Street Terminal along the Oakland Alameda Estuary. There is also a ferry terminal that serves Oakland's Jack London Square. Both of these terminals are owned and operated by the San Francisco Bay Area Water Emergency Transportation Authority (WETA). Peak time ferry service demand is at capacity. It is not unusual for passengers to be left behind at Alameda during the morning commutes, and parking demand at the facility currently outstrips available spaces. Ferry ridership at the Alameda Main Street WETA terminal is currently at 94 percent capacity and rose 12 percent in the last calendar year. WETA and the City intend to establish a commute-oriented ferry service between Seaplane Lagoon and San Francisco once operating funds and terminal and vessel assets are secured to operate the expansion service.

The Project encompasses both landside and waterside components;

however, the in-water work components are discussed in this document. Please refer to the application for more information on landside components.

The in-water sound from the pile driving and removal activities, may incidentally take seven species of marine mammals by Level B harassment only.

Dates and Duration

Project construction is proposed to begin in during early August 2019 and will be completed within approximately one year of initiation. All of the in-water work (float installation with piles and gangway) is expected to be completed within one environmental work season (August 1 to November 30). Construction will occur during weekdays and on weekends if needed. Site preparation and ground improvements will occur over one month, and could overlap with in-water work. Construction of landside improvements will require approximately 4 to 6 months. Approximately 24 total days of pile driving activities are estimated to occur, with 12 days of vibratory hammering installation and removal for template piles, 6 days of vibratory hammering for permanent piles, and 6 days of impact hammering for permanent piles. These are discussed in further detail below.

Specific Geographic Region

Seaplane Lagoon is located at the western end of Alameda Island within the 150-acre Waterfront Town Center area of Alameda Point and on the former Alameda Point Naval Air Station in Alameda, California. The project area is located along the eastern shoreline of Seaplane Lagoon, west of Ferry Point, south of West Atlantic Avenue, and north of West Oriskany Avenue (Figure 1).

Seaplane Lagoon is a rectangular basin approximately 3,000 feet (ft) by 1,600 ft. Breakwaters protect the basin from wind-generated waves, providing typically calm conditions. Seaplane Lagoon is bordered by an existing concrete and steel sheet pile bulkhead to the north, rock slope revetments to the east and west, and a breakwater with a 600-ft opening to the south. The proposed location of the ferry terminal is on the eastern shoreline of the lagoon.

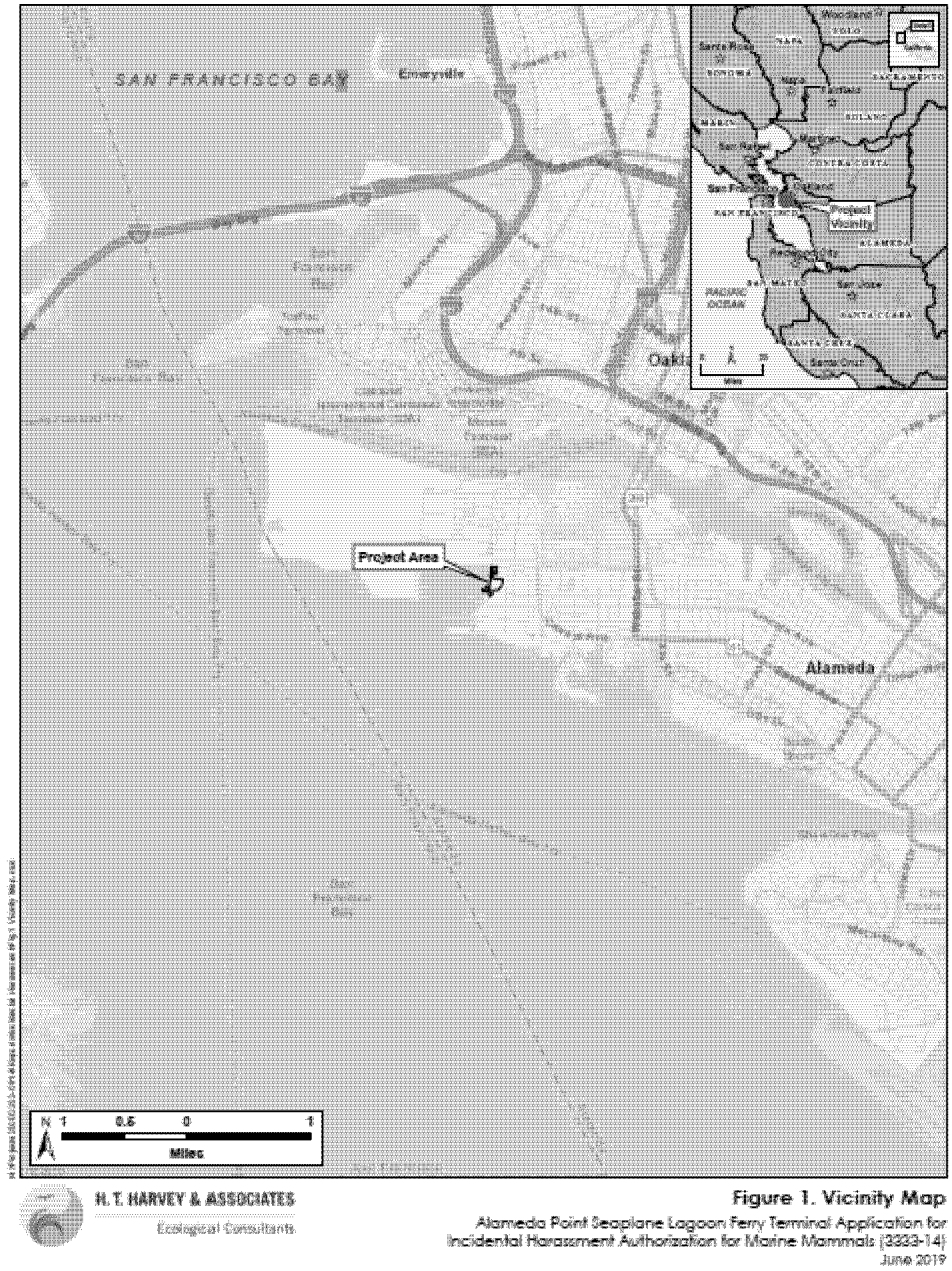

Figure 1. Project Location of Seaplane Lagoon Ferry Terminal in Alameda, California.

Detailed Description of Specific Activity

The Project encompasses both landside and waterside components, including the construction and operation of a new ferry terminal along the eastern edge of Seaplane Lagoon (see Figure 3 of the application). Only waterside components are discussed below. Please see the application for information on landside components.

A pier and abutment are required at the entrance to the ferry terminal to provide secure and safe entry from the land to the passenger access gangway (see Figure 3 of the application). The pier will extend out from the abutment to provide sufficient depth for the ferry vessels and float. The abutment will be located on the shoreline and will consist of a concrete abutment (24 feet (ft) long by 3 ft wide) supported on steel piles. The pier will be placed in the water and consist of a cast-in-place concrete structure (83.1 ft long by 20 ft wide) supported on piles with a perimeter guardrail. Approximately six 24-inch (in) diameter octagonal concrete piles offshore of the revetment and four 24-in diameter steel piles inshore of the revetment will be used for the pier. The abutment and pier deck will be installed above the high tide line.

The pier will be covered by a canopy similar to those on other San Francisco Bay Area WETA terminals in the San Francisco Bay Area. Dimensions would be longer than the pier by 16 ft (100 ft long by 20 ft wide), with an approximate height of 8.5 ft to 20 ft above the pier deck. The additional length would overhang the pier landside and shade the stairs up to the pier.

A gangway will connect the pier to the boarding float. The aluminum gangway (90 ft long by 10 ft wide) will

be supported on the landside end of the pier by cantilevered seat supports, and the waterside end of the gangway will be supported by a boarding float. The finished walking surface, which will consist of fiberglass micromesh decking, will range in elevation from 8.4 ft at the pier to approximately 4.4 ft above the water surface on the boarding float.

The Seaplane Lagoon Ferry Terminal will include a boarding float where passengers will board and disembark from the ferry (see Figure 3 of the application). The float structure will be a steel pontoon barge (135 ft long by 42 ft wide by 8 ft deep) with internal compartments. Fenders and mooring cleats will be located around the perimeter of the float to accommodate vessel berthing scenarios. The float will be held in position with an arrangement of four 36-in diameter steel guide piles and two 36-in diameter steel fender piles, totaling six piles.

Piles will be installed for the abutment, pier, and float. The 36-in steel piles will be installed with a vibratory hammer, 24-in concrete piles will be installed with an impact hammer, and 14-in steel template piles will be installed with a vibratory hammer (see Table 1 below). The abutment piles will be installed from the landside, and are expected to require an impact hammer to penetrate the underlying material. Four steel piles (the abutment piles) will be installed above the high tide line and therefore are not discussed further.

Template piles will be used to support the in-water piles. These will consist of 12 to 18 14-inch steel H-type piles (see Table 1 below). One template typically includes four piles, but up to six template piles would be used at one time (see Table 1 below).

TABLE 1—PILE DRIVING AND REMOVAL ACTIVITIES FOR SEAPLANE LAGOON FERRY TERMINAL

Description	Project component			
	Temporary template pile installation	Temporary template pile removal	Permanent pile installation	Permanent pile installation
Diameter of Steel Pile (inches)	14	14	24	36
# of Piles	18	18	6	6
Vibratory Pile Driving				
Total Quantity	18	18	0	6
Max # Piles Vibrated per Day	6	6	0	1
Impact Pile Driving				
Total Quantity	0	0	6	0
Max # Piles Impacted per Day	0	0	1	0

For further details on the proposed action and project components, please refer to the application.

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

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/find-species*).

Table 2 lists all species with expected potential for occurrence in the project area and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2016). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Pacific and SARs (Carretta *et al.,* 2018). All values presented in Table 2 are the most recent available at the time of publication (draft SARS available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

TABLE 2—MARINE MAMMALS OCCURRENCE IN THE PROJECT AREA

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, Nmin, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae:						
Gray whale	*Eschrichtius robustus*	Eastern North Pacific	-/- ; N	26,960 (0.05, 25,849, 2016).	801	138
Family Balaenopteridae (rorquals):						
Humpback whale	*Megaptera novaeangliae*	California/Oregon/Washington.	E/D ; Y	2,900 (0.048, 2,784, 2014)	16.7 (U.S. waters)	18.8
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Bottlenose dolphin	*Tursiops truncatus*	California Coastal	-/- ; N	453 (0.06, 346, 2011)	2.7	>2
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	San Francisco-Russian River.	-/- ; N	9,886 (0.51, 6,625, 2011)	66	0
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California sea lion	*Zalophus californianus*	U.S.	-/- ; N	257,606 (n/a, 233,515, 2014).	14,011	≥319
Northern fur seal	*Callorhinus ursinus*	California	-/- ; N	14,050 (n/a, 7,524, 2013)	451	1.8
		Eastern North Pacific	-/- ; N	626,734 (n/a, 530,474, 2014).	11,405	1.1
Guadalupe fur seal	*Arctocephalus townsendi*	Mexico to California	T/D ; Y	20,000 (n/a, 15,830, 2010)	542	>3.2
Family Phocidae (earless seals):						
Pacific harbor seal	*Phoca vitulina richardii*	California	-/- ; N	30,968 (n/a, 27,348, 2012)	1,641	43
Northern elephant seal	*Mirounga angustirostris*	California Breeding	-/- ; N	179,000 (n/a, 81,368, 2010).	4,882	8.8

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable [explain if this is the case].

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

NOTE—*Italicized species are not expected to be taken or proposed for authorization.*

All species that could potentially occur in the proposed survey areas are included in Table 2. However, the temporal and/or spatial occurrence of humpback whales and Guadalupe fur seals is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here.

Humpback whales do enter San Francisco Bay to feed on schooling fish from late April through October, but are rarer visitors to the interior of San Francisco Bay. A recent, seasonal influx of humpback whales inside San Francisco Bay near the Golden Gate was recorded from April to November in 2016 and 2017 (Keener 2017). In May and June 2019, a lone humpback was observed in the waters off Alameda; however, this is a rare occurrence and the whale was thought to be in poor health. The whale was observed on May 27, 2019 in the Alameda Seaplane Lagoon, where it remained until June 5, 2019. It was determined to be an adult, and malnourished, based on the thin blubber layer. On June 6, 2019, the whale re-located to an area outside the Seaplane Lagoon, but still within the breakwater protecting the Alameda ferry docks and the USS Hornet. It remained there for 8 days, exhibiting the same suite of behaviors seen in the Seaplane Lagoon. On June 14, 2019, it left Alameda and moved farther out towards the main opening of the breakwater, near the open bay (The Marine Mammal Center (TMMC), B. Keener, pers. comm. 2019) and has not been observed since. It is unlikely that this humpback whale will be in the waters off Alameda when the project begins. NMFS does expect take to occur.

Guadalupe fur seals occasionally range into the waters of northern California and the Pacific Northwest. The Farallon Islands (off central California) and Channel Islands (off southern California) are used as haul outs during these movements (Simon 2016). Juvenile Guadalupe fur seals occasionally strand in the vicinity of San Francisco, especially during El Niño events. Most strandings along the California coast are animals younger than two years old, with evidence of malnutrition (NMFS 2017a). Because Guadalupe fur seals are highly rare in the area, and sightings are associated with abnormal weather conditions, such as El Niño events, NMFS has determined that no Guadalupe fur seals are likely to occur in the project vicinity and, therefore, no take is expected to occur.

Gray Whale

Gray whales are large baleen whales. They grow to approximately 50 ft in length and weigh up to 40 tons. They are one of the most frequently seen whales along the California coast, easily recognized by their mottled gray color and lack of dorsal fin. Adult whales carry heavy loads of attached barnacles,

which add to their mottled appearance. Gray whales are divided into the Eastern North Pacific and Western North Pacific stocks. Both stocks migrate each year along the west coast of continental North America and Alaska. The Eastern North Pacific stock is much larger and is more likely to occur in the San Francisco Bay area. Western North Pacific Gray whales have summer and fall feeding grounds in the Okhotsk Sea off northeast Sakhalin Island, Russia, and off southeastern Kamchatka in the Bering Sea (NMFS 2017).

Gray whales are the only baleen whale known to feed on the sea floor, where they scoop up bottom sediments to filter out benthic crustaceans, mollusks, and worms (NMFS 2015). They feed in northern waters primarily off the Bering, Chukchi, and western Beaufort Seas during the summer. Between December and January, late-stage pregnant females, adult males, and immature females and males migrate southward to breeding areas around Mexico. The northward migration occurs between February and March. Coastal waters just outside San Francisco Bay are considered a migratory Biologically Important Area for the northward progression of gray whales (Calambokidis *et al.,* 2015). During this time, recently pregnant females, adult males, immature females, and females with calves move north to the feeding grounds (Calambokidis *et al.,* 2014). A few individuals enter into the San Francisco Bay during their northward migration. Foraging individuals in the San Francisco Bay may occur in small numbers in waters adjacent to Alameda Point, outside of the breakwaters, typically from December to May.

Since January 1, 2019, elevated gray whale strandings have occurred along the west coast of North America from Mexico through Alaska. This event has been declared an Unusual Mortality Event. As of June 21, 2019, 37 gray whales have stranded in California. Full or partial necropsy examinations were conducted on a subset of the whales. Preliminary findings in several of the whales have shown evidence of emaciation. These findings are not consistent across all of the whales examined, so more research is needed.

Bottlenose Dolphins

Bottlenose dolphins are distributed world-wide in tropical and warm-temperate waters. In many regions, including California, separate coastal and offshore populations are known (Walker 1981; Ross and Cockcroft 1990; Van Waerebeek *et al.* 1990). The California coastal stock of bottlenose dolphins is distinct from the offshore stock, based on significant differences in genetics and cranial morphology (Perrin *et al.* 2011, Lowther-Thielking *et al.* 2015). California coastal bottlenose dolphins are found within about one kilometer (km) of shore (Hansen, 1990; Carretta *et al.* 1998; Defran and Weller 1999) with the range extending north over the last several decades related to El Niño events and increased ocean temperatures. As the range of bottlenose dolphins extended north, dolphins began entering the Bay in 2010 (Szczepaniak 2013). Until 2016, most bottlenose dolphins in San Francisco Bay were observed in the western Bay, from the Golden Gate Bridge to Oyster Point and Redwood City (Perlman 2017). Members of the California Coastal stock are transient and make movements up and down the coast into some estuaries, throughout the year.

Harbor Porpoise

Harbor porpoise are seldom found in waters warmer than 62.6 degrees Fahrenheit (17 degrees Celsius) (Read 1990) or south of Point Conception, and occurs as far north as the Bering Sea (Barlow and Hanan 1995; Carretta *et al.,* 2017). The San Francisco-Russian River stock is found from Pescadero, 18 mi (30 km) south of the Bay, to 99 mi (160 km) north of the Bay at Point Arena (Carretta *et al.,* 2017). In most areas, harbor porpoise occurs in small groups, consisting of just a few individuals.

Occasional sightings of harbor porpoises in the Bay, including near the Yerba Buena Island harbor seal haul-out site, were reported by the Caltrans marine mammal monitoring program beginning in 2008 (Caltrans 2018). Continued sightings from Caltrans and the Golden Gate Cetacean Research (GGCR) Organization suggests that the species is returning to San Francisco Bay after an absence of approximately 65 years (GGCR 2010). This re-immergence is not unique to San Francisco Bay, but rather indicative of the harbor porpoise in general along the west coast. GGCR has been issued a scientific research permit from NMFS for a multi-year assessment to document the population abundance and distribution in the Bay (82 FR 60374). Recent observations of harbor porpoises have been reported by GGCR researchers off Cavallo Point, outside Raccoon Strait between Tiburon and Angel Island, off Fort Point and as far into the Bay as Carquinez Strait (Perlman 2010). Based on the Caltrans and GGCR monitoring, over 100 porpoises were seen at one time entering San Francisco Bay; and over 600 individual animals have been documented in a photo-ID database. Reported sightings are concentrated in the vicinity of the Golden Gate Bridge and Angel Island, with lesser numbers sighted south of Alcatraz and west of Treasure Island (AECOM 2017).

Harbor Seal

Harbor seals are found from Baja California to the eastern Aleutian Islands of Alaska. The species primarily hauls out on remote mainland and island beaches and reefs, and estuary areas. Harbor seals tend to forage locally within 53 miles (mi) (85 km) of haul-out sites (Harvey and Goley 2011). Harbor seal is the most common marine mammal species observed in the Bay and individuals are commonly seen near the San Francisco-Oakland Bay Bridge east span (CalTrans 2013b, 2013c). Tagging studies have shown that most seals tagged in the Bay remain in the Bay (Harvey and Goley 2011; Manugian 2013). Foraging often occurs in the Bay, as noted by observations of seals exhibiting foraging behavior (short dives less than five minutes, moving back and forth in an area, and sometimes tearing up prey at the surface). Moderate to small numbers are known to forage in Seaplane Lagoon.

Although solitary in the water, harbor seals come ashore at haul outs to rest, socialize, breed, nurse, molt, and thermoregulate. Habitats used as haul out sites include tidal rocks, bayflats, sandbars, and sandy beaches (Zeiner *et al.,* 1990). Haul out sites are relatively consistent from year to year (Kopec and Harvey 1995) and females have been recorded returning to their own natal haul out to breed (Cunningham *et al.,* 2009). Although harbor seals haul out at approximately 20 locations around San Francisco Bay, there are three primary sites: Mowry Slough in the South Bay, Corte Madera Marsh and Castro Rocks in the North Bay, and Yerba Buena Island in the Central Bay (Grigg 2008; Gibble 2011). Yerba Buena Island haul out is located approximately five mi north project area. Harbor seals use Yerba Buena Island year-round, with the largest numbers seen during winter months, when Pacific herring spawn (Grigg 2008). Two known pinniped haul-out sites in the vicinity of the project area are located on an existing haul out platform approximately 0.5 mi southeast of the project area (separated from project activities by approximately 0.3 mi of developed areas on-land), and at the western end of Breakwater Island, approximately 1.0 mi southwest of the pile driving activities (see Figure 4 of the application).

California Sea Lion

California sea lions breed on the offshore islands of California from May through July (Heath and Perrin 2009). During the non-breeding season, adult and sub-adult males and juveniles migrate northward along the coast, to central and northern California, Oregon, Washington, and Vancouver Island (Jefferson *et al.,* 1993). They return south the following spring (Lowry and Forney 2005; Heath and Perrin 2009). Females and some juveniles tend to remain closer to rookeries (Antonelis *et al.,* 1990; Melin *et al.,* 2008).

In San Francisco Bay, California sea lions have been observed at Angel Island and occupying the docks near Pier 39 which is the largest California sea lion haul-out in San Francisco Bay. A maximum of 1,706 sea lions were counted at Pier 39 in 2009. However, since then the population has averaged at about 50–300 depending upon the season (TMMC 2017). This group of sea lions has decreased in size in recent years, coincident with a fluctuating decrease in the herring population in the Bay. There are no known breeding sites within San Francisco Bay. Their primary breeding site is in the Channel Islands (USACE 2011). The sea lions appear at Pier 39 after returning from the Channel Islands at the beginning of August (Bauer 1999). No other sea lion haul out sites have been identified in the Bay and no pupping has been observed at the Pier 39 site or any other site in San Francisco Bay under normal conditions (USACE 2011). Although there has been documentation of pupping on docks in the Bay, this event was during a domoic acid event. There is no reason to anticipate that any domoic events will occur during the project construction activities.

The project site is approximately 4 mi away from Pier 39. Although there is little information regarding the foraging behavior of the California sea lion in southern San Francisco Bay, they have been observed foraging on a regular basis in the shipping channel south of Yerba Buena Island.

Foraging grounds have also been identified for pinnipeds, including sea lions, between Yerba Buena Island and Treasure Island, as well as off the Tiburon Peninsula (Caltrans, 2006). The California sea lions that use the Pier 39 haul-out site may be feeding on Pacific herring (*Clupea harengus*), northern anchovy, and other prey in the waters of San Francisco Bay (Caltrans, 2013a). In addition to the Pier 39 haul-out, California sea lions haul out on buoys and similar structures throughout San Francisco Bay. They mainly are seen swimming off the San Francisco and Marin shorelines within San Francisco Bay, but may occasionally enter the project area to forage and could possibly haul-out on nearby breakwater islands or platforms.

Northern Elephant Seal

The northern elephant seal is common on California coastal mainland and island sites, where the species pups, breeds, rests, and molts. The largest rookeries are on San Nicolas and San Miguel islands in the northern Channel Islands. Near the Bay, elephant seals breed, molt, and haul out at Año Nuevo Island, the Farallon Islands, and Point Reyes National Seashore.

Northern elephant seals haul out to give birth and breed from December through March. Pups remain onshore or in adjacent shallow water through May. Both sexes make two foraging migrations each year: One after breeding and the second after molting (Stewart 1989; Stewart and DeLong 1995). Adult females migrate to the central North Pacific to forage, and males migrate to the Gulf of Alaska to forage (Robinson *et al.* 2012). Pup mortality is high when they make the first trip to sea in May, and this period correlates with the time of most strandings. Pups of the year return in the late summer and fall, to haul out at breeding rookery and small haul out sites, but occasionally they may make brief stops in the Bay.

Generally, only juvenile elephant seals enter the Bay and do not remain long. The most recent sighting near the project area was in 2012, on the beach at Clipper Cove on Treasure Island (5 mi north of the project area), when a healthy yearling elephant seal hauled out for approximately 1 day. Approximately 100 juvenile northern elephant seals strand in or near the Bay each year, including individual strandings at Yerba Buena Island and Treasure Island (less than 10 strandings per year).

Northern Fur Seal

Northern fur seal breeds on the offshore islands of California and in the Bering Sea from May through July. Two stocks of Northern fur seals may occur near the Bay, the California and Eastern Pacific stocks. The California stock breeds, pups, and forages off the California coast. The Eastern Pacific stock breeds and pups on islands in the Bering Sea, but females and juveniles move south to California waters to forage in the fall and winter months.

Both the California and Eastern Pacific stocks forage in the offshore waters of California, but only sick, emaciated, or injured fur seals enter the Bay. The Marine Mammal Center (TMMC) occasionally picks up stranded fur seals around Yerba Buena Island and Treasure Island.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS

[NMFS 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

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

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Seven marine mammal species (3 cetacean and 4 pinniped (2 otariid and 2 phocid) species) have the reasonable potential to occur during the proposed activities. Please refer to Table 2. Of the cetacean species that may be present, one is classified as low-frequency cetacean (*i.e.,* all mysticete species), one is classified as mid-frequency cetacean (*i.e.,* all delphinid species), and one is classified as high-frequency cetacean (*i.e.,* harbor porpoise).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The *Estimated Take by Incidental Harassment* section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The *Negligible Impact Analysis and Determination* section considers the content of this section, the *Estimated Take by Incidental Harassment* section, and the *Proposed Mitigation* section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Acoustic effects on marine mammals during the specified activity can occur from vibratory and impact pile driving. The effects of underwater noise from the City's proposed activities have the potential to result in Level B harassment of marine mammals in the vicinity of the action area.

Description of Sound Sources

This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see, *e.g.,* Au and Hastings (2008); Richardson *et al.* (1995); Urick (1983).

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ''loudness'' of a sound and is typically described using the relative unit of the decibel (dB). A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)), and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of 1 m from the source (referenced to 1 μPa), while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Rms is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Rms accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 μPa^2-s) represents the total energy in a stated frequency band over a stated time interval or event, and considers both intensity and duration of exposure. The per-pulse SEL is calculated over the time window containing the entire pulse (*i.e.,* 100 percent of the acoustic energy). SEL is a cumulative metric; it can be accumulated over a single pulse, or calculated over periods containing multiple pulses. Cumulative SEL represents the total energy accumulated by a receiver over a defined time window or during an event. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure.

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam or beams or may radiate in all directions

(omnidirectional sources), as is the case for sound produced by the pile driving activity considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound, which is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 hertz (Hz) and 50 kilohertz (kHz) (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly.

The sum of the various natural and anthropogenic sound sources that comprise ambient sound at any given location and time depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 decibels (dB) from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

Sounds are often considered to fall into one of two general types: Pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts. The distinction between these two sound types is not always obvious, as certain signals share properties of both pulsed and non-pulsed sounds. A signal near a source could be categorized as a pulse, but due to propagation effects as it moves farther from the source, the signal duration becomes longer (*e.g.,* Greene and Richardson, 1988).

Pulsed sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or intermittent (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

The impulsive sound generated by impact hammers is characterized by rapid rise times and high peak levels. Vibratory hammers produce non-impulsive, continuous noise at levels significantly lower than those produced by impact hammers. Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (*e.g.,* Nedwell and Edwards, 2002; Carlson *et al.,* 2005).

Acoustic Effects on Marine Mammals

We previously provided general background information on marine mammal hearing (see *Description of Marine Mammals in the Area of the Specified Activity*). Here, we discuss the potential effects of sound on marine mammals.

Note that, in the following discussion, we refer in many cases to a review article concerning studies of noise-induced hearing loss conducted from 1996–2015 (*i.e.,* Finneran, 2015). For study-specific citations, please see that work. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can potentially result in one or more of the following: Temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We first describe specific manifestations of acoustic effects before providing discussion specific to pile driving and removal activities.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological

response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

We describe the more severe effects (*i.e.,* certain non-auditory physical or physiological effects) only briefly as we do not expect that there is a reasonable likelihood that pile driving may result in such effects (see below for further discussion). Potential effects from explosive impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.,* 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Tal *et al.,* 2015). The construction activities considered here do not involve the use of devices such as explosives or mid-frequency tactical sonar that are associated with these types of effects.

Threshold Shift—Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above (a 40-dB threshold shift approximates PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; *e.g.,* Southall *et al.* 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.

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

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaeorientalis*)) and three species of pinnipeds (northern elephant seal, harbor seal, and California sea lion) exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). TTS was not observed in trained spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to impulsive noise at levels matching previous predictions of TTS onset (Reichmuth *et al.,* 2016). In general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), Finneran (2015), and NMFS (2018).

Behavioral Effects—Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of

sources, distance from the source). Please see Appendices B–C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC, 2003; Wartzok *et al.,* 2003). Controlled experiments with captive marine mammals have showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997; Finneran *et al.,* 2003). Observed responses of wild marine mammals to loud pulsed sound sources (typically airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson *et al.,* 1995; Nowacek *et al.,* 2007). However, many delphinids approach low-frequency airgun source vessels with no apparent discomfort or obvious behavioral change (*e.g.,* Barkaszi *et al.,* 2012), indicating the importance of frequency output in relation to the species' hearing sensitivity.

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Costa *et al.,* 2003; Ng and Leung, 2003; Nowacek *et al.;* 2004; Goldbogen *et al.,* 2013a, 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.;* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Variations in respiration naturally vary with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2001, 2005, 2006; Gailey *et al.,* 2007; Gailey *et al.,* 2016).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.,* 1994).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from airgun surveys (Malme *et al.,* 1984). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement

from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans and England, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Stress Responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

Auditory Masking—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995; Erbe *et al.,* 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by

anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

Potential Effects of the City's Activity—As described previously (see *Description of Active Acoustic Sound Sources*), the City proposes to conduct pile driving, including impact and vibratory driving. The effects of pile driving on marine mammals are dependent on several factors, including the size, type, and depth of the animal; the depth, intensity, and duration of the pile driving sound; the depth of the water column; the substrate of the habitat; the standoff distance between the pile and the animal; and the sound propagation properties of the environment. With both types, it is likely that the pile driving could result in temporary, short term changes in an animal's typical behavioral patterns and/or avoidance of the affected area. These behavioral changes may include (Richardson *et al.,* 1995): Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses.

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, or reproduction. Significant behavioral modifications that could lead to effects on growth, survival, or reproduction, such as drastic changes in diving/surfacing patterns or significant habitat abandonment are extremely unlikely in this area (*i.e.,* shallow waters in modified industrial areas).

Whether impact or vibratory driving, sound sources would be active for relatively short durations, with relation to potential for masking. The frequencies output by pile driving activity are lower than those used by most species expected to be regularly present for communication or foraging. We expect insignificant impacts from masking, and any masking event that could possibly rise to Level B harassment under the MMPA would occur concurrently within the zones of behavioral harassment already estimated for vibratory and impact pile driving, and which have already been taken into account in the exposure analysis.

Anticipated Effects on Marine Mammal Habitat

The proposed activities would not result in permanent impacts to habitats used directly by marine mammals except the actual footprint of the project. The footprint of the project is small, and equal to the area the ferry associated pile placement. The installation of piles for the new pier will result in permanent impacts on 61 square feet (ft^2) of aquatic habitat. At best, the impact area, which is located in Seaplane Lagoon, provides marginal foraging habitat for marine mammals and fish. The net loss of such a small area (25 ft^2) of benthic habitat is not expected to impair the health of these species or affect their populations. Project construction and long-term operation are not expected to disturb nearby harbor seal haul-outs, which are located 1.0 mi to the southwest on Breakwater Island and 0.5 mi to the southeast on a platform installed by the City.

The proposed activities may have potential short-term impacts to food sources such as forage fish. The proposed activities could also affect acoustic habitat (see masking discussion above), but meaningful impacts are unlikely. There are no known foraging hotspots, or other ocean bottom structures of significant biological importance to marine mammals present in the marine waters in the vicinity of the project areas. Therefore, the main impact issue associated with the proposed activity would be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal prey (*i.e.,* fish) near where the piles are installed. Impacts to the immediate substrate during installation and removal of piles are anticipated, but these would be limited to minor, temporary suspension of sediments, which could impact water quality and visibility for a short amount of time, but which would not be expected to have any effects on individual marine mammals. Impacts to substrate are therefore not discussed further.

Effects to Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds which are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to

noise depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (*e.g.,* Fewtrell and McCauley, 2012; Pearson *et al.,* 1992; Skalski *et al.,* 1992; Santulli *et al.,* 1999; Paxton *et al.,* 2017). However, some studies have shown no or slight reaction to impulse sounds (*e.g.,* Pena *et al.,* 2013; Wardle *et al.,* 2001; Jorgenson and Gyselman, 2009; Cott *et al.,* 2012). More commonly, though, the impacts of noise on fish are temporary.

SPLs of sufficient strength have been known to cause injury to fish and fish mortality. However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012a) showed that a TTS of 4–6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death, and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013).

The action area supports marine habitat for prey species including large populations of anadromous fish including Pacific salmon (five species), cutthroat and steelhead trout, and Dolly Varden (NMFS 2018) and other species of marine fish such as halibut, rock sole, sculpins, Pacific cod, herring, and eulachon (NMFS 2018). The most likely impact to fish from pile driving activities at the project areas would be temporary behavioral avoidance of the area. The duration of fish avoidance of an area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the expected short daily duration of individual pile driving events and the relatively small areas being affected.

The area impacted by the project is relatively small compared to the available habitat in San Francisco Bay. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for the City's construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered to be insignificant. Effects to habitat will not be discussed further in this document.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Take of marine mammals incidental to the City's pile driving and removal activities could occur as a result of Level B harassment. Below we describe how the potential take is estimated. As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μPa (rms) for continuous (*e.g.,* vibratory pile driving) and above 160 dB re 1 μPa (rms) for impulsive sources (*e.g.,* impact pile driving). The City's proposed activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the 120 and 160 dB re 1 μPa (rms) are applicable.

Level A harassment—NMFS' *Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing* (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise. The technical guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity for all underwater anthropogenic sound sources, and reflects the best available science on the potential for noise to affect auditory sensitivity by:

- Dividing sound sources into two groups (*i.e.,* impulsive and non-

impulsive) based on their potential to affect hearing sensitivity;

- Choosing metrics that best address the impacts of noise on hearing sensitivity, *i.e.,* sound pressure level (peak SPL) and sound exposure level (SEL) (also accounts for duration of exposure); and
- Dividing marine mammals into hearing groups and developing auditory weighting functions based on the science supporting that not all marine mammals hear and use sound in the same manner.

These thresholds were developed by compiling and synthesizing the best available science, and are provided in Table 4 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance*.

The City's pile driving and removal activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving and removal) sources.

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

(Auditory Injury)

Hearing group	PTS Onset Acoustic Thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2* $L_{E,LF,24h}$: 199 dB
Mid-Frequency (MF) Cetaceans	*Cell 3* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4* $L_{E,MF,24h}$: 198 dB
High-Frequency (HF) Cetaceans	*Cell 5* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6* $L_{E,HF,24h}$: 173 dB
Phocid Pinnipeds (PW) (Underwater)	*Cell 7* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8* $L_{E,PW,24h}$: 201 dB
Otariid Pinnipeds (OW) (Underwater)	*Cell 9* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10* $L_{E,OW,24h}$: 219 dB

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

Sound Propagation

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \log_{10}(R_1/R_2)$$

Where:

B = transmission loss coefficient (assumed to be 15)

R_1 = the distance of the modeled SPL from the driven pile, and

R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each doubling of distance from the source (20*log(range)). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source (10*log(range)). As is common practice in coastal waters, here we assume practical spreading loss (4.5 dB reduction in sound level for each doubling of distance). Practical spreading is a compromise that is often used under conditions where water depth increases as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions.

Sound Source Levels

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. There are source level measurements available for certain pile types and sizes from the similar environments recorded from underwater pile driving projects (CALTRANS 2015) that were evaluated and used as proxy sound source levels to determine reasonable sound source levels likely result from the City's pile driving and removal activities (Table 5). Many source levels used were more conservation as the values were from larger pile sizes.

TABLE 5—PREDICTED SOUND SOURCE LEVELS

Activity	Sound source level at 10 meters	Sound source
Vibratory Pile Driving/Removal		
14-inch H pile steel pile temporary	155 SPL	CALTRANS 2015 (12-in H piles sound source value used, as no 14-in H pile sound source level is available)
36-inch steel pile permanent	170 SPL	CALTRANS 2015
Impact Pile Driving		
24-inch concrete pile permanent	166 SEL/176 SPL	CALTRANS 2015

Notes: These are unattentuated values, as the applicant proposes to use a bubble curtain for a 7dB reduction for impact driving.

Level A Harassment

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources (such as from impact and vibratory pile driving), NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. Inputs used in the User Spreadsheet (Tables 6 and 7), and the resulting isopleths are reported below (Table 8).

TABLE 6—NMFS TECHNICAL GUIDANCE (2018) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR VIBRATORY PILE DRIVING

User Spreadsheet Input—Vibratory Pile Driving; Spreadsheet Tab A.1 Vibratory Pile Driving Used		
	14-in H piles (temporary install/ removal)	36-in piles (permanent)
Source Level (RMS SPL)	155	170
Weighting Factor Adjustment (kHz)	2.5	2.5
Number of piles within 24-hr period	6	2
Duration to drive a single pile (min)	4	30
Propagation (xLogR)	15	15
Distance of source level measurement (meters) †	10	10

TABLE 7—NMFS TECHNICAL GUIDANCE (2018) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS FOR IMPACT PILE DRIVING

User Spreadsheet Input—Impact Pile Driving;Spreadsheet Tab E.1 Impact Pile Driving Used.	
	24-in concrete piles (permanent)
Source Level (Single Strike/shot SEL)	* 159
Weighting Factor Adjustment (kHz)	2
Number of strikes per pile	3100
Number of piles per day	1
Propagation (xLogR)	15
Distance of source level measurement (meters) *	10

* This includes the 7dB reduction from use of a bubble curtain.

TABLE 8—NMFS TECHNICAL GUIDANCE (2018) USER SPREADSHEET OUTPUTS TO CALCULATE LEVEL A HARASSMENT PTS ISOPLETHS

User Spreadsheet Output		PTS isopleths (meters)				
		Level A harassment				
Activity	Sound source level at 10 m	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency cetaceans	Phocid	Otariid
Vibratory Pile Driving/Removal						
14-in H pile steel installation/removal	155 dB SPL	1.5	0.1	2.2	0.9	0.1
36-in steel permanent installation	170 dB SPL	13.1	1.2	19.3	7.9	0.6
Impact Pile Driving						
24-in concrete permanent installation.	166 SEL/176 SPL (159 dB SEL as attenuated).	53.3	1.9	63.5	28.5	2.1

Level B Harassment

Utilizing the practical spreading loss model, the City determined underwater noise will fall below the behavioral effects threshold of 120 dB rms for marine mammals at the distances shown in Table 9 for vibratory pile driving/removal. For calculating the Level B Harassment Zone for impact driving, the practical spreading loss model was used with a behavioral threshold of 160 dB rms for marine mammals at the distances shown in Table 9 for impact pile driving. Table 9 below provides all Level B Harassment radial distances (m) and their corresponding areas (km^2) during the City's proposed activities.

TABLE 9—RADIAL DISTANCES (meters) TO RELEVANT BEHAVIORAL ISOPLETHS AND ASSOCIATED ENSONIFIED AREAS (SQUARE KILOMETERS (km^2)) USING THE PRACTICAL SPREADING MODEL

Activity	Received level at 10 m	Level B harassment zone (m) *	Level B harassment zone (km^2)
Vibratory Pile Driving/Removal			
14-inch H piles installation/removal	155 dB SPL	2,154	2.190
36-inch steel permanent installation	170 dB SPL	21,544	21.49
Impact Pile Driving			
24-inch concrete permanent installation	166 dB SEL/176 dB SPL (169 dB SPL attenuated)	39.8	0.004

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. Potential exposures to impact pile driving and vibratory pile driving/removal for each acoustic threshold were estimated using group size estimates and local observational data to create a density estimate. As previously stated, take by Level B harassment only will be considered for this action. Distances to Level A harassment thresholds are relatively small and mitigation is expected to avoid Level A harassment from these activities.

Gray Whales

There are no density estimates of gray whales available in the project area. Gray whales travel alone or in small, unstable groups, although large aggregations may be seen in feeding and breeding grounds (NMFS 2018). Gray whales are uncommon in the San Francisco Bay. It is estimated that approximately 2–6 individuals enter the bay in a typical year (CALTRANS 2018). However nine gray whales have stranded in the San Francisco Bay in 2019 (Katz 2019). To be conservative, NMFS proposes to authorize seven instances of take by Level B harassment of gray whales. Because the required shutdown measures are larger than the associated Level A harassment zones, and those zones are relatively small (53.3 m at the largest during impact pile driving), and activities will occur over a small number of days, we believe the PSO will be able to effectively monitor the Level A harassment zones and we do not anticipate take by Level A harassment of gray whales.

Bottlenose Dolphin

There are no density estimates of Bottlenose dolphin available in the project area. Individuals in the San Francisco Bay are typically sighted near the Golden Gate Bridge, where an average of five dolphins enter the bay approximately three times annually. Two individuals are sighted regularly near Alameda Point, outside of the Seaplane Lagoon (CALTRANS 2018). Low numbers (ranging from 1 to 5) of individually identified coastal bottlenose dolphins have been seen

along the southwest side of Alameda Island since July 2016. Much of the time, the dolphins were close to the south side of the main outer breakwater that separates the bay from the lagoon areas. The last reliable sighting there was April 7, 2019 of a single individual (TMMC, B. Keener pers. comm. 2019). For the purpose of this assessment it is predicted that two bottlenose dolphins may occur in the San Francisco Bay in the Project vicinity on all pile driving days (*i.e.,* up to 48 individuals in 24 days. Therefore, NMFS proposes to authorize 48 instances of take of bottlenose dolphin by Level B harassment. The Level A harassment zones are all under 2 m for mid-frequency cetaceans; therefore, no take by Level A harassment is anticipated.

Harbor Porpoise, Harbor Seals, and California Sea Lions

In-water densities of harbor porpoises, harbor seals, California sea lions were calculated based on 17 years of observations during monitoring for the San Francisco Bay-Oakland Bay Bridge (SFOBB) construction and demolition project (Caltrans 2018). Care was taken to eliminate multiple observations of the same animal, although this can be difficult and is likely that the same individual may have been counted multiple times on the same day. The amount of monitoring performed per year varied, depending on the frequency and duration of construction activities with the potential to affect marine mammals. During the 257 days of monitoring from 2000 through 2017 (including 15 days of baseline monitoring in 2003), 1,029 harbor seals, 83 California sea lions, and 24 harbor porpoises were observed in waters in the project vicinity in total. In 2015, 2016, and 2017, the number of harbor seals in the project area increased significantly. A California sea lion density estimate of 0.161 animals/km^2 was calculated using the data from 2000–2017. In 2017, the number of harbor porpoise in the project area also increased significantly. Therefore, a harbor seal density estimate of 3.957 animals/km^2 was calculated using the 2015–2017 data. A harbor porpoise density estimate of 0.167 animals/km^2 was calculated using the 2017 data, which may better reflect the current use of the project area by these animals. These observations included data from baseline, pre-, during, and post-pile driving, mechanical dismantling, on-shore blasting, and off-shore implosion activities.

In addition to the information provided above regarding harbor seal density estimates, harbor seals are known to use the tip of Breakwater Island, which is located approximately 1.0 mi southwest of the project area, as a haul-out site. These seals forage in the project area as well (WETA 2011). In recent years, up to 32 harbor seals have been observed making irregular use of the Breakwater Island haul-out (AECOM 2017). The City of Alameda has also recently installed a haul-out platform approximately 0.5 mi southeast of the site. Although these locations are not considered primary haul-outs for harbor seals due to the relatively low numbers of individuals that are present, Breakwater Island and the City haul-out platform are reportedly the only haul-out sites in the central Bay that are accessible to seals throughout the full tidal range.

A local group of Alameda Point Harbor Seal Monitors regularly counts the number of harbor seals at Alameda Point, and based on count data from 2014 to 2019 an average of 11.7 harbor seals is present at Alameda Point year-round (Bangert pers. comm. 2019 in the application). However, the numbers of harbor seals present in the area varies considerably with season, with higher numbers in the winter due to the presence of spawning Pacific herring (*Clupea pallasii*) in the San Francisco Bay. Project pile driving activities will occur during the months of August and September, and therefore we estimated the average number of harbor seals based on count data these months only. The data summary indicated that the numbers of harbor seals present at Alameda increased in 2017 and 2018 compared to 2015 and 2016, and therefore only count data from 2017 and 2018 was used to ensure that the density estimate reflects current conditions. The average number of harbor seals counted at Alameda Point in August and September of 2017 and 2018 was 6.5 individuals. These densities described above for harbor porpoise, harbor seals, and California sea lions are then used to calculate estimated take and described in the sub-sections below for these species.

Harbor Porpoise

A predicted density of 0.167 animals/km^2 based for harbor porpoise was used to estimate take (Table 10). The estimated take was calculated using this density multiplied by the area ensonified above the threshold multiplied by the number of days per activity (*e.g.,* 6 days of impact pile driving) (Table 10). Therefore, a total of 26 instances of take by Level B harassment are proposed for harbor porpoise. Because the required shutdown measures are larger than the associated Level A harassment zones, and the harassment zones ar not very larger (63.5 m at the largest during impact pile driving), and will only occur over a small number of days, we believe the PSO can effectively monitor the Level A harassment zones and therefore we do not anticipate take by Level A harassment of harbor porpoise.

TABLE 10—PROPOSED ESTIMATED TAKE BY LEVEL B HARASSMENT OF HARBOR PORPOISE

Source	Density (animals/km^2)	Area (km^2)	Days of activity	Proposed Level B take by harassment
Vibratory Installation and Removal 14-in H piles	0.167	2.190	12	4.389
Vibratory 36-in piles	0.167	21.490	6	21.533
Impact 24-in piles	0.167	0.004	6	0.004
Total Take by Level B harassment	.....	.....	.....	25.926 (rounded to 26)

Harbor Seal

A predicted a density of 3.957 animals/km^2 for harbor seals was used to estimate take by Level B harassment (Table 11). This density should account for harbor seals exposed in the water while moving to and from the breakwater haul out since those animals would be in the bay and accounted for

by the density estimate. The estimated take was calculated using this density multiplied by the area ensonified above the threshold multiplied by the number of days per activity (*e.g.,* 6 days of impact pile driving) (Table 11). Therefore, a total of 615 instances of take by Level B harassment are proposed for harbor seals. Because the required shutdown measures are larger than the associated Level A harassment zones, and those zones are relatively small (28.5 m at the largest during impact pile driving), we believe the PSO can effectively monitor the Level A harassment zones and therefore we do not anticipate any take by Level A harassment of harbor seals.

TABLE 11—PROPOSED ESTIMATED TAKE BY LEVEL B HARASSMENT OF HARBOR SEAL

Source	Density (animals/km^2)	Area (km^2)	Days of activity	Proposed Level B take by harassment
Vibratory Installation and Removal 14-in H piles	3.957	2.190	12	103.999
Vibratory 36-in piles	3.957	21.490	6	510.216
Impact 24-in piles	3.957	0.004	6	0.095
Total Take by Level B harassment	.....	.....	.....	614.31 (rounded to 615)

California Sea Lions

A predicted a density of 0.161 animals/km^2 based for California sea lions was used to estimate take by Level B harassment (Table 12). The estimated take was calculated using this density multiplied by the area ensonified above the threshold multiplied by the number of days per activity (*e.g.,* 6 days of impact pile driving) (Table 12). Therefore, a total of 25 instances of take by Level B harassment are proposed for California sea lions. The Level A harassment zones are all under 2.1 m for otariids; therefore, no take by Level A harassment of California sea lions is anticipated.

TABLE 12—PROPOSED ESTIMATED TAKE BY LEVEL B HARASSMENT OF CALIFORNIA SEA LIONS

Source	Density (animals/km^2)	Area (km^2)	Days of activity	Proposed Level B take by harassment
Vibratory Installation and Removal 14-in H piles	0.161	2.190	12	4.231
Vibratory 36-in piles	0.161	21.490	6	20.759
Impact 24-in piles	0.161	0.004	6	0.004
Total Take by Level B harassment	.....	.....	.....	24.994 (rounded to 25)

Northern Elephant Seal

There are no density estimates of northern elephant seals available in the project area. Elephant seals breed between December and March and have been rarely cited in San Francisco Bay. It is anticipated that if an elephant seal is encountered at all during pile driving or drilling it would be a juvenile. For the purpose of this assessment, we predict that up to one northern elephant seal may occur in the San Francisco Bay in the Project vicinity on up to 20 percent of pile driving days (*i.e.,* up to 4.8 individuals in 24 days). This assumption is consistent with the recent IHA for the demolition and reuse of the marine foundations of the original east span of the San Francisco-Oakland Bay Bridge (CALTRANS 2018). Therefore, NMFS proposes to authorize five takes (0.2 seals/day multiplied by 24 project days) by Level B harassment of elephant seals. Because the required shutdown measures are larger than the associated Level A harassment zones, and those zones are relatively small (28.5 m at the largest during impact pile driving), we believe the PSO can effectively monitor the Level A harassment zones and therefore we do not anticipate any take by Level A harassment of northern elephant seals.

Northern Fur Seals

There are no density estimates of northern fur seals available in the project area. The Marine Mammal Center (TMMC) reported only two to four northern fur seal strandings in the Bay in 2015 and 2016 (in Marin, San Francisco, and Santa Clara counties) (TMMC 2017). To account for the possible rare presence of the species in the action area, NMFS proposes to authorize three takes by Level B harassment of northern fur seals. The Level A harassment zones are all under 2.1 m for otariids; therefore, no take by Level A harassment of Northern fur seals is anticipated.

Table 13 below summarizes the proposed estimated take for all the species described above as a percentage of stock abundance.

TABLE 13—PROPOSED TAKE ESTIMATES AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Stock (N_{EST})	Level A harassment	Level B harassment	Percent of stock
Gray Whale	Eastern North Pacific (26,960)	0	7	Less than 1 percent.

TABLE 13—PROPOSED TAKE ESTIMATES AS A PERCENTAGE OF STOCK ABUNDANCE—Continued

Species	Stock (N_{EST})	Level A harassment	Level B harassment	Percent of stock
Bottlenose Dolphin	California Coastal (453)	0	48	10.596 percent.
Harbor Porpoise	San Francisco-Russian River (9,886)	0	27	Less than one percent.
Harbor Seal	California (30,968)	0	615	Less than 2 percent.
Northern Elephant Seal	California Breeding (179,000)	0	5	Less than one percent.
California Sea Lion	U.S. (257,606)	0	25	Less than one percent.
Northern fur seal	Eastern DPS, California (20,000)	0	3	Less than one percent.

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned); and

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The following mitigation measures are proposed in the IHA:

Timing Restrictions

All work will be conducted during daylight hours. If poor environmental conditions restrict visibility full visibility of the shutdown zone, pile installation would be delayed.

Sound Attenuation

To minimize noise during impact pile driving, a 12-inch thick wood cushion block will be used. Bubble curtains will be also used during any impact pile driving of piles located in the water. The bubble curtain will be operated in a manner consistent with the following performance standards:

a. The bubble curtain will distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column;

b. The lowest bubble ring will be in contact with the mudline for the full circumference of the ring, and the weights attached to the bottom ring shall ensure 100 percent mudline contact. No parts of the ring or other objects shall prevent full mudline contact; and

c. Air flow to the bubblers must be balanced around the circumference of the pile.

Soft Start

Soft start requires contractors to provide an initial set of strikes at reduced energy, followed by a thirty-second waiting period, then two subsequent reduced energy strike sets. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or longer.

Shutdown Zone for In-Water Heavy Machinery Work

For in-water heavy machinery work other than pile driving, if a marine mammal comes within 10 m of such operations, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions.

Shutdown Zones

For all pile driving/removal and drilling activities, the City will establish shutdown zones for a marine mammal species that is greater than its corresponding Level A harassment zone. The calculated PTS isopleths were rounded up to a whole number to determine the actual shutdown zones that the applicant will operate under (Table 14). The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area).

TABLE 14—PILE DRIVING SHUTDOWN ZONES DURING PROJECT ACTIVITIES

Activity	Shutdown Zones (radial distance in meters, area in km^{2*})				
	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency cetaceans	Phocid	Otariid
In-Water Construction Activities					
Heavy machinery work (other than pile driving).	10 (0.00015 km^2)	10 (0.00015 km^2)	10 (0.00015 km^2)	10 (0.00015 km^2)	10 (0.00015 km^2)
Vibratory Pile Driving/Removal					
14-in H pile steel installation/removal	10 (0.00015 km^2	10 (0.00015 km^2	10 (0.00015 km^2	10 (0.00015 km^2	10 (0.00015 km^2

TABLE 14—PILE DRIVING SHUTDOWN ZONES DURING PROJECT ACTIVITIES—Continued

Activity	Shutdown Zones (radial distance in meters, area in km²*)				
	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency cetaceans	Phocid	Otariid
36-in steel permanent installation	15 (0.00035 km²)	10 (0.00015 km²)	20 (0.00063 km²)	10 (0.00015 km²)	10 (0.00015 km²)
Impact Pile Driving					
24-in concrete permanent installation	55 (0.00475 km²)	10 (0.00015 km²)	65 (0.00663 km²)	30 (0.00141 km²)	10 (0.00015 km²)

*Note: km² were divided by two to account for land.

Non-Authorized Take Prohibited

If a species enters or approaches the Level B zone and that species is either not authorized for take or its authorized takes are met, pile driving and removal activities must shut down immediately using delay and shut-down procedures. Activities must not resume until the animal has been confirmed to have left the area or an observation time period of 15 minutes has elapsed for pinnipeds and small cetaceans and 30 minutes for large whales.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth, requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Pre-Activity Monitoring

Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 min or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 min. The shutdown zone will be cleared when a marine mammal has not been observed within the zone for that 30-min period. If a marine mammal is observed within the shutdown zone, pile driving activities will not begin until the animal has left the shutdown zone or has not been observed for 15 min. If the Level B Harassment Monitoring Zone has been observed for 30 min and no marine mammals (for which take has not been authorized) are present within the zone, work can continue even if visibility becomes impaired within the Monitoring Zone. When a marine mammal permitted for Level B harassment take has been permitted is present in the Monitoring zone, piling activities may begin and Level B harassment take will be recorded.

Monitoring Zones

The City will establish and observe monitoring zones for Level B harassment as presented in Table 9. The monitoring zones for this project are areas where SPLs are equal to or exceed 120 dB rms (for vibratory pile driving/removal) and 160 dB rms (for impact pile driving). These zones provide utility for monitoring conducted for mitigation purposes (*i.e.,* shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of the Level B harassment zones enables observers to be aware of and communicate the presence of marine mammals in the project area, but outside the shutdown zone, and thus prepare for potential shutdowns of activity.

Visual Monitoring

Monitoring would be conducted 30 minutes before, during, and 30 minutes after all pile driving/removal and socking/rock anchoring activities. In addition, PSO shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven/removed. Pile driving/removal activities include the time to install, remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes.

Monitoring will be conducted by PSOs from on land. The number of PSOs will vary from one to two, depending on the type of pile driving, method of pile driving and size of pile, all of which determines the size of the harassment zones. Monitoring locations will be selected to provide an unobstructed view of all water within the shutdown zone and as much of the Level B harassment zone as possible for pile driving activities. A single monitor will be present during impact pile driving, when impacts of the project

will be limited to the area within the Alameda Lagoon, and two monitors will be present during vibratory pile driving when project impacts will extend into the waters of the San Francisco Bay.

In addition, PSOs will work in shifts lasting no longer than 4 hours with at least a 1-hour break between shifts, and will not perform duties as a PSO for more than 12 hours in a 24-hour period (to reduce PSO fatigue).

Monitoring of pile driving shall be conducted by qualified, NMFS-approved PSOs, who shall have no other assigned tasks during monitoring periods. The City shall adhere to the following conditions when selecting PSOs:

- Independent PSOs shall be used (*i.e.,* not construction personnel);
- At least one PSO must have prior experience working as a marine mammal observer during construction activities;
- Other PSOs may substitute education (degree in biological science or related field) or training for experience;
- Where a team of three or more PSOs are required, a lead observer or monitoring coordinator shall be designated. The lead observer must have prior experience working as a marine mammal observer during construction; and
- The City shall submit PSO CVs for approval by NMFS for all observers prior to monitoring.

The City shall ensure that the PSOs have the following additional qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Experience and ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior;
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary; and
- Sufficient training, orientation, or experience with the construction operations to provide for personal safety during observations.

Acoustic Monitoring

The City has developed a sound attenuation monitoring plan to protect fish and marine mammals during pile driving activities (see Appendix B of the application for further details). The acoustic monitoring will include documentation of the following, at a minimum:

- Hydrophone equipment and methods: recording device, sampling rate, distance from the pile where recordings were made; and depth of recording device(s);
- Type of pile being driven and method of driving during recordings; and
- Mean, medium, and maximum sound levels (dB re: 1µPa): cumulative sound exposure level, peak sound pressure level, rms sound pressure level, and single-strike sound exposure level.

Reporting of Injured or Dead Marine Mammals

In the unanticipated event that the planned activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as serious injury, or mortality, the City must immediately cease the specified activities and report the incident to the NMFS Office of Protected Resources and the West Coast Region Stranding Coordinator. The report must include the following information:

- Time and date of the incident;
- Description of the incident;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations and active sound source use in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s).

Activities must not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with the City to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The City may not resume their activities until notified by NMFS.

In the event the City discovers an injured or dead marine mammal, and the lead observer determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), the City must immediately report the incident to the Office of Protected Resources, NMFS, and the West Coast Region Stranding Coordinator, NMFS. The report must include the same information as the bullets described above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with the City to determine whether additional mitigation measures or modifications to the activities are appropriate.

In the event that the City discovers an injured or dead marine mammal, and the lead observer determines that the injury or death is not associated with or related to the specified activities (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the City must report the incident to the Office of Protected Resources, NMFS, and the West Coast Region Stranding Coordinator, NMFS, within 24 hours of the discovery.

Final Report

The City shall submit a draft report to NMFS no later than 90 days following the end of construction activities or 60 days prior to the issuance of any subsequent IHA for the project. The City shall provide a final report within 30 days following resolution of NMFS' comments on the draft report. Reports shall contain, at minimum, the following:

- Date and time that monitored activity begins and ends for each day conducted (monitoring period);
- Construction activities occurring during each daily observation period, including how many and what type of piles driven;
- Deviation from initial proposal in pile numbers, pile types, average driving times, etc.;
- Weather parameters in each monitoring period (*e.g.,* wind speed, percent cloud cover, visibility);
- Water conditions in each monitoring period (*e.g.,* sea state, tide state);
- For each marine mammal sighting:
  - Species, numbers, and, if possible, sex and age class of marine mammals;
  - Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
  - Type of construction activity that was taking place at the time of sighting;

- Location and distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- If shutdown was implemented, behavioral reactions noted and if they occurred before or after shutdown.
- Estimated amount of time that the animals remained in the Level A or B Harassment Zone.

- Description of implementation of mitigation measures within each monitoring period (*e.g.,* shutdown or delay);
- Other human activity in the area within each monitoring period;
- A summary of the following:
  - Total number of individuals of each species detected within the Level B Harassment Zone, and estimated as taken if correction factor appropriate;
  - Total number of individuals of each species detected within the Level A Harassment Zone and the average amount of time that they remained in that zone; and
  - Daily average number of individuals of each species (differentiated by month as appropriate) detected within the Level B Harassment Zone, and estimated as taken, if appropriate.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

As stated in the proposed mitigation section, shutdown zones that are larger than the Level A harassment zones and are expected avoid the likelihood of Level A harassment for all seven species.

Exposures to elevated sound levels produced during pile driving activities may cause behavioral disturbance of marine mammals, but they are expected to be mild and temporary. Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006; Lerma, 2014). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. These reactions and behavioral changes are expected to subside quickly when the exposures cease.

To minimize noise during pile driving, and thereby both the scale and potential severity of the anticipated effects, the City will use pile cushions and a bubble curtain during impact pile driving.

During all impact driving, implementation of soft start procedures and monitoring of established shutdown zones will be required, significantly reducing the possibility of injury. Given sufficient notice through use of soft start (for impact driving), marine mammals are expected to move away from an irritating sound source prior to it becoming potentially injurious. In addition, PSOs will be stationed within the action area whenever pile driving/removal activities are underway. Depending on the activity, the City will employ one to two PSOs to ensure all monitoring and shutdown zones are properly observed.

Two known pinniped haul-out sites (non-pupping sites) are located in the vicinity of the project area. One is an existing haul out platform approximately 0.5 mi southeast of the project area (separated from project activities by approximately 0.3 mi of developed areas on-land). The second haul out is the western end of Breakwater Island, approximately 1.0 mi southwest of the location of pile driving activities (Figure 4 of the application). They are both well outside the PTS isopleths for pinnipeds and no Level A harassment is expected. Exposures to elevated sound levels produced during pile driving activities once the animals enter the water from the haul outs may cause behavioral responses by an animal, but they are expected to be mild and temporary and limited to Level B harassment,

The proposed activities would not result in permanent impacts to habitats used directly by marine mammals except the actual footprint of the project. The footprint of the project is small, and equal to the area the ferry associated pile placement. The installation of piles for the new pier will result in permanent impacts on 61 ft^2 of aquatic habitat. At best, the impact area, which is located in Seaplane Lagoon, provides marginal foraging habitat for marine mammals and fish. In addition, impacts to marine mammal prey species are expected to be minor and temporary. Overall, the area impacted by the project is very small compared to the available habitat in the bay. The most likely impact to prey will be temporary behavioral avoidance of the immediate area. During pile driving/removal activities, it is expected that fish and marine mammals would temporarily move to nearby locations and return to the area following cessation of in-water construction activities. Therefore, indirect effects on marine mammal prey during the construction are not expected to be substantial.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated;
- No Level A Harassment is anticipated or proposed for authorization;
- Minimal impacts to marine mammal habitat are expected;
- The action area is located and within an active marine commercial area;
- There are no rookeries, or other known areas or features of special significance for foraging or reproduction in the project area;
- Anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior; and
- The required mitigation measures (*i.e.* shutdown zones and pile cushion, and bubble curtain) are expected to be

effective in reducing the effects of the specified activity.

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

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The take of six marine mammal stocks proposed for authorization comprises less than two percent of the stock abundance, and less than 11 percent for bottlenose dolphins (California coastal).

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action.

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. No ESA listed species are proposed for take. Therefore, NMFS has determined consultation under the ESA is not required.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the City for conducting for the proposed pile driving and removal activities for construction of the Alameda Seaplane Lagoon ferry terminal for one year, beginning August 2019, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed pile driving and removal activities for construction of the ferry terminal. We also request comment on the potential for renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

- On a case-by-case basis, NMFS may issue a one-year IHA renewal with an additional 15 days for public comments when (1) another year of identical or nearly identical activities as described in the Specified Activities section of this notice is planned or (2) the activities as described in the Specified Activities section of this notice would not be completed by the time the IHA expires and a second IHA would allow for completion of the activities beyond that described in the Dates and Duration section of this notice, provided all of the following conditions are met. A request for renewal is received no later than 60 days prior to expiration of the current IHA.
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take because only a subset of the initially analyzed activities remain to be completed under the Renewal); and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized;

- Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: July 15, 2019.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–15299 Filed 7–17–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit modifications.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427–8401; fax: (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Erin Markin (Permit No. 21858–01), Jennifer Skidmore (Permit No. 20610–01), and Sara Young (Permit Nos. 22289, 22293, and 22298); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the research, go to *www.federalregister.gov* and search on the permit number provided in the table below.

Permit No.	RIN	Applicant	Previous **Federal Register** notice	Permit or amendment issuance date
20610–01 ...	0648–XF801	David Portnoy, Ph.D., Texas A&M University, Corpus Christi, TX 78412.	84 FR 24103; May 24, 2019 ..	June 27, 2019
21858–01 ...	0648–XG332	NMFS Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester MA 01930 (Responsible Party: Julie Crocker).	84 FR 20618; May 10, 2019 ..	June 25, 2019.
22289	0648–XG913	Alaska Fisheries Science Center's Marine Mammal Laboratory (MML), 7600 Sand Point Way NE, Seattle, WA 98115–0070 (Responsible Party: John Bengtson).	84 FR 15597; April 16, 2019 ..	June 21, 2019.
22293	0648–XG913	Alaska Sea Life Center (ASLC), P.O. Box 1329, 301 Railway Avenue, Seward, AK 99664 (Responsible Party: Tara Reimer).	84 FR 15597; April 16, 2019 ..	June 21, 2019.
22298	0648–XG913	Alaska Department of Fish and Game (ADF&G), P.O. Box 25526, Juneau, AK 99802–5526 (Responsible Party: Michael Rehberg).	84 FR 15597; April 16, 2019 ..	June 21, 2019.

For Permit Nos. 20610–01 and 21585–01, in compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment (EA) or environmental impact statement (EIS).

For Permit Nos. 22289, 22293, and 22298, a determination was made that the activities authorized are consistent with the Preferred Alternative in the Final Programmatic EIS for Steller Sea Lion and Northern Fur Seal Research (NMFS 2007). A supplemental EA (NMFS 2014) was prepared for the addition of unmanned aerial surveys to the suite of Steller sea lion research activities analyzed under the EIS and concluded that issuance of the permits would not have a significant adverse impact on the human environment. An environmental review memo was prepared to summarize these findings.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: July 15, 2019.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–15304 Filed 7–17–19; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, July 24, 2019; 1:30 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting.

MATTER TO BE CONSIDERED: Recreational Off-Highway Vehicles (ROV).

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: July 16, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–15429 Filed 7–16–19; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, July 24, 2019; 9:00 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting.

MATTER TO BE CONSIDERED: Refrigerator Safety Act Policy Statement.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: July 16, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–15427 Filed 7–16–19; 4:15 pm]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, July 24, 2019; 10:00 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting.

MATTER TO BE CONSIDERED: The National Academy of Science (NAS) will brief the Commission on Organohalogen Flame Retardant Scoping and Feasibility Plan.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: July 16, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–15428 Filed 7–16–19; 4:15 pm]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for Senior Corps Project Progress Report

AGENCY: Corporation for National and Community Service (CNCS).

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, CNCS is proposing to renew an information collection, Senior Corps Project Progress Report (PPR). CNCS and grantees use the Senior Corps PPR data track performance and inform continued grant funding support, as well as to identify trends and to support management and analysis.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by September 16, 2019.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, Attention Jill Sears, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except federal holidays.

(3) Electronically through *www.regulations.gov.*

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Anne Otih, (202) 606–7570, or by email at *aotih@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Senior Corps Project Progress Report.

OMB Control Number: 3045–0033.

Type of Review: Renewal.

Respondents/Affected Public: Sponsors of Senior Corps grants.

Total Estimated Number of Annual Responses: 1,100.

Total Estimated Number of Annual Burden Hours: 17,600 (Work plans and narratives, semi-annual: Four hours per response. Progress Report Supplemental, annual: Eight hours per response).

Abstract: The Progress Report (PPR) was designed to ensure that grantees of the Senior Corps' programs (RSVP, Foster Grandparent and Senior Companion Programs) address and fulfill legislated program purposes; meet agency program management and grant requirements; track and measure progress to benefit the local project and its contributions to senior volunteers and the community; and to report progress toward work plan objectives agreed upon in the granting of the award. The resulting data is used by grantees and CNCS to track performance and inform continued grant funding support, as well as to identify trends and to support management and analysis. CNCS seeks to renew and revise the current OMB approved PPR to align with recent national performance measures changes and to remove administrative burdens.

CNCS also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on December 31, 2019.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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. All written comments will be available for public inspection on *regulations.gov.*

Dated: July 15, 2019.

Deborah Cox-Roush,

Director, Senior Corps.

[FR Doc. 2019–15278 Filed 7–17–19; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2019–HQ–0024]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice of a modified System of Records.

SUMMARY: The Department of the Army proposes to modify a System of Records Notice (SORN), Army Personnel Systems (APS), A0600–8–104 AHRC. This system of records is comprised of Human Resources (HR) information required to manage a Soldier's career from initial accession through separation, and for life for retirees. Currently APS records are managed by 36 information technology (IT) systems that are linked to seven System of Records Notices (SORNs). In a cost saving effort to eliminate redundant functions and discordant IT systems, the Army is transitioning HR and military pay records for Soldiers to the Integrated Personnel and Pay System-Army (IPPS–A).

DATES: This notice is effective upon publication; however, comments on the Routine Uses will be accepted on or before August 19, 2019. The Routine Uses are effective are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

• *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Tracy Rogers, Department of the Army, U.S. Army Records Management and Declassification Agency, ATTENTION: Army Privacy and Civil Liberties Office, 9301 Chapek Road (Building 1458), Fort Belvoir, VA 22060–5605, or by calling 571–515–0248.

SUPPLEMENTARY INFORMATION: Currently the APS is a virtual network of disparate IT systems and electronic record sets that collectively document personnel actions over the course of a Soldier's military service. As the Army's new enterprise personnel and pay system, IPPS–A will organize, collect, and maintain fragmented HR records in a single IT system. These records are currently maintained in 44 IT systems of which 36 are linked to seven existing HR SORNs (including this notice). The IPPS–A will fully subsume the 36 systems and partially subsume records from eight additional HR and military pay systems. The system provides a single record of service for each Soldier. It will provide Combatant Commanders real-time accurate force strength and readiness, better tracking of personnel into and out of theaters of operations, and will enhance mission planning and support. IPPS–A is designed to fully integrate military personnel and pay capabilities for the Active Army, Army National Guard, and Army Reserves. When fully deployed, Soldiers will have access to view segments of their APS records via IPPS–A and initiate select personnel actions. In addition, IPPS–A will provide new functionality which will enable HR professionals to manage military pay actions for Soldiers. Through the initiative known as the Military Pay (MilPay) Transition, the scope of the APS will expand to include data from the Defense Finance and Accounting Services (DFAS) required to administer military pay actions. IPPS–A's ability to combine personnel and pay functions (*e.g.,* a promotion or call to Active Duty) will address current inefficiencies caused by complex interfaces among outdated and disparate HR systems. As a result, IPPS–A will leave fewer opportunities for error and will become the authoritative and comprehensive source of Army personnel and pay functions. When fully implemented, IPPS–A will provide a secure, web-based integrated personnel and pay system to support the Army's peacetime and wartime readiness requirements for human resource management.

This notice merges six other existing Army HR SORNs: A0600–8 AHRC, Individual Ready, Standby, and Retired Reserve Personnel Information System; A0600–8–23 AHRC, Standard Installation/Division Personnel System; A0600–8a PEO EIS, Integrated Personnel and Pay System—Army Records; A0614–200 AHRC, Classification and Reclassification of Soldiers; A0680–31a AHRC, Officer Personnel Management Information System; A0680–31b AHRC Enlisted Personnel Management Information System. These SORNs were thoroughly reviewed and the information has been properly incorporated in this notice. The six notices identified for consolidation will be rescinded after this notice goes into effect. The DoD is publishing the notice in its entirety to comply with current standards and formatting requirements prescribed in OMB Circular A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication Under the Privacy Act.''

The Department of the Army's notices for system of records subject to the Privacy Act of 1974, as amended, have been published in the **Federal Register** and are available from the address in the **FOR FURTHER INFORMATION CONTACT** section or from the Defense Privacy, Civil Liberties, and Transparency Division website at *https://dpcld.defense.gov/*.

The proposed systems reports, as required by the Privacy Act, as amended, were submitted on May 7, 2019, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication Under the Privacy Act,'' December 23, 2016 (December 23, 2016, 81 FR 94424).

Dated: July 12, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Army Personnel Systems (APS), A0600–8–104 AHRC.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Primary location: U.S. Army Human Resources Command, 1600 Spearhead Division Avenue, Fort Knox, KY 40122–5500. Secondary locations: U.S. Army Reserve Command G–1, 4710 Knox Street, Fort Bragg, NC 28310–5010.

Army National Guard Readiness Center, 111 South George Mason Drive, Arlington, VA 22204–1382. General Officer Management Office, Office of the Chief of Staff, Army, 200 Pentagon, Washington, DC 20310–0200. Fort Hood Garrison, Directorate of Human Resources, 18010 Battalion Ave, Ft. Hood, TX 76544.

SYSTEM MANAGER(S):

Director of Military Personnel Management, Army G1, U.S. Army Human Resources Command, 1600 Spearhead Division Avenue, AHRC–PDV, Fort Knox, KY 40122–5500. Project Manager, Integrated Personnel and Pay System-Army (IPPS–A), IPPS–A Product Management Office (PMO), U.S. Army Program Executive Office Enterprise Information Systems, James Polk Building, 2521 South Clark Street Arlington, VA 22202.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. Subtitle A, General Military Law, Part II, Personnel (Chapters 31–41, 43, 45, 47–51, 53, 55–61, 63, 65, 67, 69, 71, 73, 75–77, 79, 80, 87–88) and Part III, Training and education (Chapters 101–107, 109–112); 10 U.S.C. 7013, Secretary of the Army; 10 U.S.C. Subtitle B, Army, Part II, Personnel (Chapters 711, 713, 715, 719, 721, 723, 725, 729, 733, 735, 737, 741, 743, 745, 749) and Part III, Training (Chapters 751, 753, 757); 10 U.S.C. Subtitle E, Reserve Components, Part II, Personnel Generally (Chapters 1201–1225), Part III, Promotion and Retention of Officers on the Reserve Active Status List, (Chapters 1401–1411), and Part IV, Training for Reserve Components and Educational Assistance Programs (Chapters 1601–1611); 18 U.S.C. 3771, Crime victims' rights; 37 U.S.C., Pay and Allowances Of the Uniformed Services; Department of Defense Directive (DoDD) 1030.01, Victim and Witness Assistance; DoDD 1200.7, Screening the Ready Reserve;

DoDD 1300.22, Mortuary Affairs Policy; Department of Defense Instruction (DoDI) 1235.12, Accessing the Reserve Components (RC); DoDI 1300.15, Military Funeral Support; DoDI 1300.18, Department of Defense (DoD) Personnel Casualty Matters, Policies, and Procedures; DoDI 1300.19, DoD Joint Officer Management (JOM) Program; DoDI 1304.30, Enlisted Personnel Management Plan (EPMP) Procedures; DoDI 1310.01, Rank and Seniority of Commissioned Officers; DoDI 1320.04, Military Officer Actions Requiring Presidential, Secretary of Defense, Or Under Secretary of Defense for Personnel and Readiness Approval or Senate Confirmation; DoDI 1320.14, Commissioned Officer Promotion Program Procedures; DoDI 1332.18, Disability Evaluation System (DES); DoDI 1332.35, Transition Assistance Program (TAP) for Military Personnel; DoDI 1336.05, Automated Extract of Active Duty Military Personnel Records; DoDI 1336.08, Military Human Resource Records Life Cycle Management; DoD 1352.01, Management of Regular and Reserve Retired Military Members; DoD 7000.14–R, Department of Defense Financial Management Regulation (DoD FMR); DoDI 7730.54, Reserve Components Common Personnel Data System (RCCPDS); Army Regulation (AR) 37–104–4, Military Pay and Allowances Policy; AR 55–46, Travel Overseas; AR 55–355, Military Traffic Management Regulation; AR 135–133, Ready Reserve Screening, Qualification Records System, and Change of Address Reporting; AR 135–155, Promotion of Commissioned Officers and Warrant Officers Other Than General Officers; AR 140–1, Mission, Organization, and Training; AR–140–9, Entry on Active Duty or Active Duty for Training (ROTC Officers); AR 140–10, Assignments, Attachments, Details, and Transfers; AR 140–50, Officer Candidate School, Army Reserve; AR 140–111, U.S. Army Reserve Reenlistment Program; AR 140–145, Individual Mobilization Augmentation Program; AR 600–8, Military Human Resources Management; AR 600–8–6, Personnel Accounting and Strength Reporting; AR 600–8–7, Retirement Services Program; AR 600–8–10; Leaves and Passes; AR 600–8–14, Identification Cards for Members of the Uniformed Services, their Family Members and Other Eligible Personnel; AR 600–8–19, Enlisted Promotions and Reductions; AR 600–8–22, Military Awards; AR 600–8–24, Officer Transfers and Discharges; AR 600–8–29, Officer Promotions; AR 600–37, Unfavorable Information; AR 600–43, Conscientious Objection; AR 600–81, Soldier for Life—Transition Assistance Program; AR 600–85, The Army Substance Abuse Program; AR 600–101, Personnel Processing (In-, Out-, Soldier Readiness, and Deployment Cycle); AR 600–8–104, Army Military Human Resource Records Management; AR 600–8–111, Wartime Replacement Operations; AR 601–10, Management and recall to Active Duty of retired Soldiers of the Army in Support of Mobilization and Peacetime Operations; AR 601–100, Appointment of Commissioned and Warrant Officers in the Regular Army; AR 601–210, Regular Army and Reserve Components Enlistment Program; AR 601–280, Army Retention Program; AR 608–18, The Family Advocacy Program; AR 608–75, Exceptional Family Member Program; AR 614–30, Overseas Service; AR 614–100, Officer Assignment Policies, Details, and Transfers; AR 614–200, Enlisted Assignments and Utilization Management; AR 621–5, Army Continuing Education System; AR 623–3, Evaluation Reporting System; AR 630–10, Absent Without Leave, Desertion, and Administration of Personnel Involved in Court Proceedings; AR 635–40, Disability Evaluation for Retention, Retirement, or Separation; AR 635–200, Active Duty Enlisted Separations; AR 638–2, Army Mortuary Affairs Program; AR 638–8, Army Casualty Program; AR 640–30, Official Army Photographs; AR 930–4, Army Emergency Relief; and Executive Order 9397 (SSN).

PURPOSE(S) OF THE SYSTEM:

The APS provides human resources capabilities in support of peacetime and wartime readiness requirements for the Army. The records in APS are created and maintained to manage the Soldier's career, administer benefits, historically document military service, and to safeguard the Soldier's rights while in service of the nation. Army leaders and commanders rely on APS information to make recommendations and document decisions pertaining to advancements, job classification, retention, assignments, recognition, disciplinary actions, and other personnel actions. The Army Human Resources Command and Army personnel offices at all echelons of command use the information in this system of records to manage all aspects of an individual's Army career to include: Accession, retention, job classification, benefits, duty assignments, deployments, career progression, performance evaluations, military training, separation or retirement, and military awards and decorations. Further, with implementation of the Military Pay Transition, APS will include management of Soldier's pay entitlements, allowances, and recording of indebtedness to the Federal government.

The Army will leverage the capabilities of the Integrated Personnel and Pay System-Army (IPPS–A) to perform most automated personnel functions. As the Army's enterprise information technology system for human resource management, IPPS–A will be the primary repository for APS data. IPPS–A provides a platform to streamline human resource business processes, assess manpower trends, administer readiness functions, and perform longitudinal statistical analyses necessary for force management. When fully implemented, IPPS–A will provide a secure, web-based integrated personnel and pay system to support the Army's peacetime and wartime readiness requirements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All members of the United States Army to include: Active Army, National Guard, Reserve, Military Technicians (Title 5 and Title 32), U.S. Military Academy Cadets, and Army Reserve Officers' Training Corps contracted cadets, Officer Candidates, and Enlisted basic trainees; all former members of the United States Army who were separated by discharge, retirement, death, or other termination of military status.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personally identifying data to include: Full name and other names used; Social Security Number (SSN) or individual tax payer identification number (ITIN); DoD Identification (DoD ID) number; gender; date and place of birth; race and ethnic origin; height, weight, eye color; blood type; official and identification photographs; government issued passport number; driver's license number; and Army Knowledge Online (AKO) login;

Other personal data to include: Marital status; citizenship and immigration status; religious preference; home and mobile telephone number; home and mailing address; state of permanent residence; personal email address; languages spoken; emergency contact information; and survivor beneficiary information (amounts of coverage; dates of beginning and ending eligibility);

Dependent family member data to include: Family members' full name and other names used; SSN or ITIN; DoD ID number; gender; date and place of birth; marital status; citizenship and immigration status; dependent

eligibility and enrollment forms; government issued passport number; home, mobile and work telephone number; and home and work address. For spouses who are members of the uniformed services, military personnel data to include: Service, rank/grade; organization and unit of assignment; personnel category code; assignment preferences and duty status;

Duty and employment data to include: Pay grade and rank; military occupational specialty and skill qualification identifier; official duty title; security clearance level and investigation type; unit of assignment; duty phone number and address; military or civilian supervisor's name and contact information; official and AKO email addresses. Civil service occupational series, civilian pay plan, and grade for Military Technicians;

Military personnel data to include: Performance reports; promotion selection data; officer commissioning and appointment documents; warrant officer appointments; enlisted accession and reenlistment documents; job classification documentation; aptitude test results; skill and special qualifications; military service computation dates; duty assignment history and projections; duty command of assignment; effective date of duty assignment; deployment information; expiration of term of service; retirement and separation documentation; field/application for active duty; Guard and Reserve activations and retirement points; discharge and separation reviews; application for correction of military records; personnel and medical board determinations; background investigation data; moral and personnel waivers; special duty applications; enlistment bonus contracts; language/foreign language qualifications; benefits eligibility and enrollments; awards and decorations; adverse actions and misconduct determinations; Uniform Code of Military Justice (UCMJ) actions summarizing court martial; conscientious objector reports; Absent Without Leave (AWOL) and deserter reports; and other related personnel orders and military service information.

Education data to include: Civilian education information pertaining to education level, transcripts, professional certifications, and licenses. Military education information pertaining to courses attended, attendance dates and completion status, and special recognitions;

Medical readiness data to include: Casualty incident reports; physical health assessment data; physical profile qualification and limitations; physical fitness testing results; disability determinations; substance abuse referrals; and behavioral health profiles.

Pay and compensation data to include: Earnings and allowances; special pay and bonuses; travel authorizations and vouchers; payroll deductions; allotments; garnishments; indebtedness and tax levy documentation; savings bond information; Thrift Savings Plan (TSP) enrollment; payroll computations, payroll balances and history; direct deposit information (financial institution name, routing number, account number); leave requests and balances; and substantiating documents that establish, support, reduce, or cancel entitlements.

RECORD SOURCE CATEGORIES:

The individual; supervisors and commanders; third parties when information furnished relates to the individual's military service; the individual's Official Military Personnel File, military medical records, and other official Army records. Personnel, pay, and benefit data is also received from records maintained by DoD and Uniformed Service agencies to include: The Defense Manpower Data Center, Defense Finance and Accounting Service, Defense Health Agency, and Defense POW/MIA Accounting Agency. Information may also be provided by education and financial institutions, law enforcement agencies, the American Red Cross, the Office of Personnel Management, Department of Veteran Affairs, Department of Homeland Security, Department of Treasury, and other Federal, state and local agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. Section 552a(b) of the Privacy Act of 1974, as amended, the records contained in this system may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. Section 552a(b)(3) as follows:

a. To the Office of the President of the United States of America for the purpose of exchanging required information relating to White House Fellows, regular Army promotions, aides, and related support functions staffed by Army members.

b. To officials and employees of the Office of the Sergeant at Arms of the United States House of Representatives for the purpose of the performance of their official duties related to the verification of the active duty military service of Members of Congress. Access is limited to those portions of the member's record required to verify time in service.

c. To the Department of State for the purpose of documenting persona non grata status, attaché assignments, and related administration of personnel assigned and performing duty with the Department of State.

d. To the Bureau of Citizenship and Immigration Services, Department of Homeland Security, for the purposes of making alien admission and naturalization inquiries; and facilitating the verification of individuals who may be eligible for expedited naturalization (Pub. L. 108–136, Section 1701, and E.O. 13269, Expedited Naturalization).

e. To the Social Security Administration for the purpose of substantiating applicant's credit for social security compensation, to report earned wages by members for the Federal Insurance Contribution Act (FICA), accounting or tax audits, and death notices.

f. To the Department of Treasury for the purpose of providing information on check issues and electronic funds transfers.

g. To the Department of Treasury, Bureau of the Fiscal Service for the purpose of facilitating distribution of pay for personnel in trainee status using EZpay and to provide deployed personnel with the option to utilize EagleCash.

h. To the Internal Revenue Service for the purpose of reporting taxable earnings and taxes withheld, accounting, and tax audits, and to compute or resolve tax liability or tax levies.

i. To the National Finance Center, Office of Thrift Savings Plan (TSP), for the purpose of starting, changing, or stopping of contributions to the individual's TSP as well as how the individual wants the investments to be made in the various TSP Funds.

j. To State Agencies for the purpose of supporting State Veteran Affairs activities.

k. To the Social Security Administration, Office of Disability and Insurance Security Programs, for the purpose of expediting disability processing of wounded military service members and veterans.

l. To the Department of Labor for the purpose of determinining eligibility for unemployment compensation for former Service members who have applied for unemployment through state or territory government benefit offices.

m. To officials and employees of the Department of Health and Human Services for the purpose of the performance of their official duties related to eligibility, notification, and

assistance in obtaining benefits for which members, former members, or retirees may be eligible.

n. To the Selective Service System for the purpose of facilitating compliance of members and former members of the Armed Forces, both active and reserve, with the provisions of the Selective Service registration regulations (50 U.S.C. Chapter 49).

o. To the American Red Cross for the purpose of providing emergency notification and financial relief to members of the Armed Forces, retirees, family members or survivors.

p. To military relief societies (Army Emergency Relief, Navy-Marine Corps Relief Society, Air Force Aid Society, and Coast Guard Mutual Assistance, Inc.) for the purpose of providing financial assistance and other relief-related services to military personnel and their dependents.

q. To consumer reporting agencies for the purpose of disclosures pursuant to 5 U.S.C. 552a(b)(12) 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)). The purpose of this disclosure is to aid in the collection of outstanding debts owed to the Federal government, typically to provide an incentive for debtors to repay delinquent Federal government debts by making these debts part of their credit records. Disclosure is limited to information necessary to establish the identity of the individual, including name, address, and taxpayer identification number (Social Security Number); the amount, status, and history of the claim; and the agency or program under which the claim arose for the sole purpose of allowing the consumer reporting agency to prepare a commercial credit report.

r. To federal and state licensing authorities and civilian certification boards, committees and/or ecclesiastical endorsing organizations for the purposes of professional credentialing (licensing and certification) of lawyers, chaplains, health professionals, and other certifications identified by the Department of Defense.

s. To Federal agencies, their contractors and grantees, and to private organizations, such as the National Academy of Sciences, for the purposes of conducting personnel and/or health-related research in the interest of the Federal government and the public. When not considered mandatory, the names and other identifying data will be eliminated from records used for such research studies.

t. To the widow or widower, dependent, or next-of-kin of deceased members for the purpose of settling the affairs of the deceased member. The individuals will have to verify relationship by providing a birth certificate, marriage license, death certificate, or court document as requested/required to prove identity.

u. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government when necessary to accomplish an agency function related to this system of records.

v. To designated officers and employees of Federal, State, local, territorial or tribal, international, or foreign agencies maintaining civil, criminal, enforcement, or other pertinent information, such as current licenses, if necessary to obtain information relevant and necessary to a DoD Component decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

w. To designated officers and employees of Federal, State, local, territorial, tribal, international, or foreign agencies in connection with the hiring or retention of an employee, the conduct of a suitability or security investigation, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter and the Department deems appropriate.

x. To contractors whose employees require suitability determinations, security clearances, and/or access to classified national security information, for the purpose of ensuring that the employer is appropriately informed about information that relates to and/or may impact a particular employee or employee applicant's suitability or eligibility to be granted a security clearance and/or access to classified national security information.

y. To a former DoD employee for the purpose of responding to an official inquiry by a Federal, State, local, territorial or tribal entity or professional licensing authority, in accordance with applicable DoD regulations; or for the purpose of facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the DoD requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

z. To foreign or international law enforcement, security, or investigatory authorities to comply with requirements imposed by, or to claim rights conferred in, international agreements and arrangements, including those regulating the stationing and status in foreign countries of DoD military and civilian personnel.

aa. To State and local taxing authorities with which the Secretary of the Treasury has entered into agreements under 5 U.S.C. 5516, 5517, or 5520 and only to those state and local taxing authorities for which an employee or military member is or was subject to tax, regardless of whether tax is or was withheld. The information to be disclosed is information normally contained in Internal Revenue Service (IRS) Form W–2.

bb. To any person, organization or governmental entity (*e.g.,* local governments, first responders, American Red Cross, etc.), in order to notify them of or respond to a serious and imminent terrorist or homeland security threat or natural or manmade disaster as is necessary and relevant for the purpose of guarding against or responding to such threat or disaster.

cc. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

dd. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

ee. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

ff. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

gg. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

hh. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the

request of, the individual who is the subject of the record.

ii. To appropriate agencies, entities, and persons when (1) the DoD suspects or has confirmed that there has been a breach of the system of records; (2) the DoD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

jj. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in paper and electronic storage media, in accordance with the safeguards as stated below.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved primarily by use of the individual's name, SSN, DoD ID number, and/or date of birth.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

All records in the APS are maintained in accordance with Army records maintenance and disposition schedules and the requirements of the National Archives and Records Administration. The retention periods for information in this system of records varies from temporary to permanent.

Personnel-type orders are maintained by the Army office of records for two years, then transferred to the Washington National Records Center and destroyed after 54 years.

Approved military award case files that are related to wartime and/or combat activities are treated as permanent and offered to the National Archives and Records Administration 20 years after the close of the conflict to which they relate.

Military pay records, due to the Military Pay Transition, the disposition is pending until the National Archives and Records Administration has approved the retention and disposition schedule, treat as permanent. Individuals with pay dates prior to 1 January 2019 should refer to Defense Finance and Accounting Service system of records notices T7340, Defense Joint Military Pay System-Active Component and T7344, Defense Joint Military Pay System-Reserve Component.

Certain items not considered rights and interests records are maintained in the current filing area until no longer needed, but no longer than six years. Upon expiration, documents are purged and destroyed.

Certain items that evidences benefits or significant personnel actions are filed in the individual's Official Military Personnel Record for permanent retention (see Army system of records notice A0600–8–104b AHRC, Official Military Personnel Record).

Records are disposed of according to the provisions of 44 U.S.C., Chapter 33, Disposal of Records and DoD Manual 5200.01, Volume 4, DoD Information Security Program: Controlled Unclassified Information (CUI).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper and electronic records are protected in accordance with policies in DoD Manual 5200.01, Volume 4, DoD Information Security Program: Controlled Unclassified Information (CUI). Electronic records are also protected in accordance with policies in DoDI 8510.01, DoD Risk Management Framework (RMF) for DoD Information Technology (IT). Records are stored in secured buildings, physical access requires identification and is limited to individuals having an official requirement for entry. System data are encrypted, and access to data and data storage is controlled and limited to authorized personnel who are properly trained, screened, and cleared for need-to-know, and access is further restricted by requiring use of a Common Access Card and PIN and/or strong passwords that are changed periodically according to DoD and Army security policies.

In-depth physical, technical, and administrative controls have been established to safeguard electronic data. Users are required to successfully undergo and complete a National Agency Check with Inquiries along with a credit check. Role-based access to the system is managed by the HRC access control procedures and policies. All aspects of privacy, security, configuration, operations, data retention, and disposal are documented to ensure privacy and security are consistently enforced and maintained.

RECORDS ACCESS PROCEDURES:

Individuals seeking access to records about them contained in this system should contact their supporting military personnel division or address written inquiries to the commander of the organization to which the service member is assigned as follows:

For information on active duty, retired and non-unit reserve personnel contact the U.S. Army Human Resources Command, Attn: AHRC–PDR–H, 1600 Spearhead Division Avenue, Fort Knox, KY 40122–5500.

For information on reserve personnel assigned to Troop Program Units contact U.S. Army Reserve Command G–1, 4710 Knox Street, Fort Bragg, NC 28310–5010.

For information on Army National Guard personnel contact the National Guard Bureau, Army National Guard Readiness Center, 111 South George Mason Drive, Arlington, VA 22204–1382.

For information on General Officers contact the General Officer Management Office, Office of the Chief of Staff, Army, 200 Pentagon, Washington, DC 20310–0200.

For information on discharged and deceased personnel contact the National Personnel Records Center, 1 Archives Drive, St. Louis, MO 63138–1002.

Individuals should provide the full name, SSN, DoD ID number or service identification number if applicable, current address, telephone number, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial agency determinations are contained in 32 CFR part 310 or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals seeking access to records about them contained in this system

should contact their supporting military personnel division or address written inquiries to the commander of the organization to which the service member is assigned as follows:

For information on active duty, retired and non-unit reserve personnel, contact the U.S. Army Human Resources Command, Attn: AHRC–PDR–H, 1600 Spearhead Division Avenue, Fort Knox, KY 40122–5500.

For information on reserve personnel assigned to Troop Program Units contact U.S. Army Reserve Command G–1, 4710 Knox Street, Fort Bragg, NC 28310–5010.

For information on Army National Guard personnel contact the National Guard Bureau, Army National Guard Readiness Center, 111 South George Mason Drive, Arlington, VA 22204–1382.

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In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

July 30, 2013, 78 FR 45914; January 6, 2004, 69 FR 790; December 8, 2000, 65 FR 77002; December 19, 1997, 62 FR 66606; February 22, 1993, 58 FR 10166.

[FR Doc. 2019–15242 Filed 7–17–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2019–0044; OMB Control Number 0704–0434]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS); Radio Frequency Identification Advance Shipment Notices

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

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use through September 30, 2019. DoD proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by September 16, 2019.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0434, using any of the following methods:

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

Email: osd.dfars@mail.mil. Include OMB Control Number 0704–0434 in the subject line of the message.

Fax: 571–372–6094.

Mail: Defense Acquisition Regulations System, Attn: Ms. Carrie Moore, OUSD(A&S)DPC(DARS), 3060 Defense Pentagon, Room 3B941, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided.

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

SUPPLEMENTARY INFORMATION:

Title, Associated Form, and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS); Radio Frequency Identification Advance Shipment Notices; OMB Control Number 0704–0434.

Needs and Uses: DoD uses advance shipment notices for the shipment of material containing Radio Frequency Identification (RFID) tag data. DoD receiving personnel use the advance shipment notice to associate the unique identification encoded on the RFID tag with the corresponding shipment. Use of the RFID technology permits DoD an automated and sophisticated end-to-end supply chain that has increased visibility of assets and permits delivery of supplies to the warfighter more quickly.

Affected Public: Businesses or other for-profit and not-for profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Type of Request: Extension.

Number of Respondents: 5,217.

Responses per respondent: 3,782.

Annual Responses: 19,732,850.

Average Burden per Response: Approximately 1.16 seconds.

Annual Burden Hours: 6,353.

Summary of Information Collection

The clause at DFARS 252.211–7006, Passive Radio Frequency Identification, requires the contractor to ensure that the data on each passive RFID tag are unique and conform to the requirements that they are readable and affixed to the appropriate location on the specific level of packaging in accordance with MIL–STD–129 tag placement specifications. The contractor shall encode an approved RFID tag using the appropriate instructions at the time of contract award. Regardless of the selected encoding scheme, the contractor is responsible for ensuring that each tag contains a globally unique identifier. The contractor shall electronically submit advance shipment notices with the RFID tag identification in advance of the shipment in accordance with the procedures at *https://wawf.eb.mil/.*

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2019–15253 Filed 7–17–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket DARS–2019–0043]

Defense Federal Acquisition Regulation Supplement: Public Meetings on DFARS Cases Regarding Technical Data Rights

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

ACTION: Announcement of public meetings.

SUMMARY: DoD is hosting public meetings to obtain views of experts and interested parties in Government and the private sector regarding amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement statutory amendments and revisions to policies and procedures for the acquisition of technical data and computer software and associated license rights.

DATES:

Public Meeting Dates: The public meetings will be held on the following dates:

- September 6, 2019, from 9:00 a.m. to 12:00 p.m., Eastern time.
- September 16, 2019, from 1:00 p.m. to 4:00 p.m., Eastern time.

The public meetings will end at the stated times, or when the discussion ends, whichever comes first.

Registration Dates: Registration to attend the public meetings must be received no later than close of business on the following dates:

- August 30, 2019, for the meeting on September 6th.
- September 9, 2019, for the meeting on September 16th.

Information on how to register for the public meetings may be found in the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES: The two public meetings will be held in the Mark Center Auditorium, 4800 Mark Center Drive, Alexandria, VA 22350–3603. The Mark Center Auditorium is located on level B–1 of the building.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, telephone 571–372–6100.

SUPPLEMENTARY INFORMATION: DoD is hosting public meetings to obtain the views of experts and interested parties in Government and the private sector regarding amending the DFARS to implement statutory amendments and revise policies and procedures for acquisition of technical data and computer software, and associated license rights. DoD also seeks to obtain information on the potential increase or decrease in public costs or savings that would result from such amendments to the DFARS. In addition to the statutory changes, DoD is considering recommendations related to that statutory subject matter that were provided in the November 13, 2018, Final Report of the Government-Industry Advisory Panel on Technical Data Rights (Section 813 Panel), established pursuant to section 813 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016.

To facilitate discussion at the public meetings, DoD anticipates publication of advance notices of proposed rulemaking, which will include initial drafts of the DFARS amendments, prior to the public meetings. This approach is based in part on a recommendation of the Section 813 Panel to invite industry to participate in the drafting of rules concerning technical data rights. For the two public meetings listed in the **DATES** section of this notice, DoD anticipates discussion of the following DFARS cases:

- 2018–D069, Validation of Proprietary and Technical Data, which implements section 865 of the NDAA for FY 2019.
- 2018–D071, Negotiation of Price for Technical Data and Preference for Specially Negotiated Licenses, which implements section 835 of the NDAA for FY 2018 and section 867 of the NDAA for FY 2019.

After these two meetings, DoD anticipates scheduling and hosting additional public meetings, structured in the same manner and for the same overall objective, to address the following DFARS cases:

- 2018–D070, Continuation of Technical Data Rights during Challenges, which implements section 866 of the NDAA for FY 2018.
- 2018–D018, Noncommercial Computer Software, which implements section 871 of the NDAA for FY 2018.
- A new case that will implement section 809 of the NDAA for FY 2017.
- A new case that will implement section 815 of the NDAA for FY 2012, as amended by section 809 of the NDAA for FY 2017.

Registration: To ensure adequate room accommodations and to facilitate security screening and entry to the Mark Center, individuals wishing to attend the public meeting must register by close of business on the dates listed in the **DATES** section of this notice, by sending the following information via email to *osd.dfars@mail.mil:*

(1) Full name.

(2) Valid email address.

(3) Valid telephone number.

(4) Company or organization name.

(5) Whether the individual is a U.S. citizen.

(6) The date(s) of the public meeting(s) the individual wishes to attend.

(7) Whether the individual intends to make a presentation, and, if so, the individual's title.

Building Entry: Upon receipt of an email requesting registration, the Defense Acquisition Regulations System will provide notification to the Pentagon Force Protection Agency (PFPA) that the individual is requesting approval for entry to the Mark Center on the date(s) provided. PFPA will send additional instructions to the email address provided in the request for registration. The registrant must follow the instructions in the PFPA email in order to be approved for entry to the Mark Center.

One valid government-issued photo identification card (*i.e.,* driver's license or passport) will be required in order to enter the building.

Attendees are encouraged to arrive at least 30 minutes prior to the start of the meeting to accommodate security procedures.

Public parking is not available at the Mark Center.

Presentations: If you wish to make a presentation, please submit an electronic copy of your presentation to *osd.dfars@mail.mil* no later than the registration date for the specific meeting listed in the **DATES** section of this notice. Each presentation should be in PowerPoint to facilitate projection during the public meeting and should include the presenter's name, organization affiliation, telephone number, and email address on the cover page. Please submit presentations only and cite ''Public Meeting, DFARS Technical Data Rights Cases'' in all correspondence related to the public meeting. There will be no transcription at the meeting. The submitted presentations will be the only record of the public meeting and will be posted to the following website at the conclusion of the public meeting: *https://www.acq.osd.mil/dpap/dars/technical_data_rights.*

Special accommodations: The public meeting is physically accessible to persons with disabilities. Requests for reasonable accommodations, sign language interpretation, or other auxiliary aids should be directed to Daniel Weinstein, telephone 571–672–6105, by no later than the registration date for the specific meeting listed in the **DATES** section of this notice.

The TTY number for further information is: 1–800–877–8339. When the operator answers the call, let him or her know the agency is the Department of Defense and the point of contact is Daniel Weinstein at 571–672–6105.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2019–15255 Filed 7–17–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare a Draft NEPA Document for the Upper St. Anthony Falls Lock and Dam Disposition Study, Hennepin County, Minnesota

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent to initiate public scoping and prepare an Environmental Assessment (EA).

SUMMARY: The St. Paul District, Army Corps of Engineers (Corps) is conducting a study regarding the disposition of the Upper St. Anthony Falls Lock and Dam (USAF) located at river mile 853.9 on the Upper Mississippi River, in Hennepin County, Minnesota. The study will include an environmental assessment and consider modifications that could improve the overall quality of the environment in the public interest, including removal of federally-owned facilities. The study will evaluate three types of alternatives: (1) No action; (2) de-authorization and disposal of all federally-owned and operated facilities; and (3) partial de-authorization and disposal of features or separable elements not required for flood mitigation operations. The study will also explore opportunities to improve the overall quality and health of the environment and/or enhance recreation. It is anticipated that a preliminary draft report of the integrated Disposition Study and Environmental Assessment (EA) will be available for a minimum 30-day public comment period in the Spring of 2020. The St. Paul District of the Army Corps of Engineers is soliciting public comments on the scope of the proposed study and significant issues that should be analyzed in the EA.

DATES:

Scoping Meetings: The Corps will hold public scoping meetings at the following times and locations during the scoping period:

▪ Tuesday, August 13th, 2019 from 6:00 p.m. to 8:00 p.m. at the Mill City Museum, 704 South Second Street, Minneapolis, Minnesota 55401.

▪ Monday, August 19th, 2019 from 6:00 p.m. to 8:00 p.m. at the Michael Dowling School, 3900 West River Parkway, Minneapolis, Minnesota 55406.

At the scoping meetings, the public is encouraged to submit resource information, and identify topics to be considered in the development of the EA. Public meetings will include a presentation and question and answer session. The Corps will require formal comments to be provided in writing, which will be accepted at the meetings or may be submitted at any time during the comment period.

Comments: The Corps will accept comments received or postmarked on or before October 20, 2019. Any comments received after the closing date may not be considered.

ADDRESSES: Comments may be submitted by one of the following methods:

Email—Written comments should be sent to: *MplsLocksDisposition@usace.army.mil.*

Mail/Courier—Written comments should be sent to: District Engineer, U.S. Army Corps of Engineers, St. Paul District, ATTN: Regional Planning and Environment Division North, 180 Fifth Street East, Suite 700, St. Paul, Minnesota 55101–1678

Comment Card—Comment cards provided as part of the public meetings will be collected at the end of the meeting or can be mailed to the address in the MAIL/COURIER section above.

If submitting comments by email, the following should be included in the subject line or first line of the message ''USAF Disposition Study Comments''.

FOR FURTHER INFORMATION CONTACT: To have your name added to a mailing list for notices related to the preliminary draft report and EA or additional public meetings, submit an email request to *MplsLocksDisposition@usace.army.mil.* General questions about the study may be directed to Nan Bischoff, Project Manager, U.S. Army Corps of Engineers, St. Paul District, 180 Fifth Street East, Suite 700, St. Paul, MN 55101–1678; telephone (651) 290–5426; email: *Nanette.m.bischoff@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The Corps operates USAF, located on the Mississippi River in Minneapolis, Minnesota. Section 2010 of the Water Resources Reform and Development Act of 2014, Public Law 113–121, directed the Corps to close the lock to navigation operations but to continue to carry out emergency operations necessary to mitigate flood damages. Navigation at the lock ceased on June 9th, 2015. Prior to the closure of USAF, the lock operated as part of a system to support navigation on the upper reaches of the Mississippi River 9-foot navigation channel. With the lock at USAF now closed to navigation, the demand for both commercial and recreational lockage has decreased at Lower St. Anthony Falls Dam (LSAF) and Lock and Dam 1 (LD 1). A disposition study for LSAF and LD 1 will be conducted separately from the disposition study for USAF, and will follow a similar public scoping procedure. The LSAF and LD 1 disposition study is scheduled to begin in early 2021.

Section 216 of the Flood Control Act of 1970 authorizes the Secretary of the Army to review operations of completed projects, when found advisable due to changed physical, economic, or environmental conditions. Disposition studies are a specific type of Section 216 study with the intent to determine whether a water resources development project operated and maintained by the Corps of Engineers should be de-authorized and the associated real property and Government-owned improvements disposed of. An Initial Appraisal (IA) was conducted by the Corps in 2015 to determine if conditions exist which may warrant further analysis on a completed project as authorized by Section 216. The IA recommended investigation under this authority regarding the future use or disposition of USAF as well as LSAF and LD 1.

The Corps began a disposition study for USAF, LSAF, and LD 1 in early 2018 with the intent that all three sites would be studied and presented in one report. Public scoping meetings for a combined study were held in July 2018. The combined disposition study was put on hold following the enactment of the Water Resources Development Act of 2018 (WRDA 2018). WRDA 2018 contains two sections pertinent to the scope and timing of the disposition studies: Section 1168, entitled ''Disposition of Projects'' and Section 1225, entitled ''Upper Mississippi River protection''. The full version of the WRDA 2018 may be found here: *https://www.congress.gov/bill/115th-congress/senate-bill/3021/.*

Following enactment of WRDA 2018, the Corps of Engineers solicited input and published implementation guidance for WRDA 2018, Sections 1168 and 1225. Input was provided by U.S. Senators Amy Klobuchar and Tina Smith of Minnesota, the National Park Service, the Friends of the Lock and

Dam and the city of Minneapolis. The implementation guidance to Sections 1168 and 1225 of WRDA 2018 may be found here: *https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/Legislative-Links/wrda__2018/wrda2018__impguide/*.

The USAF Disposition Study will analyze three types of alternatives at the USAF site: (1) The no action; (2) complete de-authorization by Congress of the Federal missions at the site and disposal of the properties; and (3) partial de-authorization and disposal. In addition, the study will examine opportunities to augment these three alternatives by considering measures which: (1) Preserve recreational opportunities; (2) enhance recreational opportunities; (3) preserve the health of the ecosystem; (4) enhance the health of the ecosystem; (5) maintain the benefits to the natural ecosystem; and (6) maintain the benefits to the human environment. The partial disposition alternative will maintain the flood control capability of the structure. If the Corps determines that Federal interest no longer exists, it must consider, and may recommend, removal of the project or separable elements of the project under existing authorities.

In accordance with the National Environmental Policy Act of 1969 (NEPA), an Environmental Assessment (EA) for this study is anticipated and will be prepared by the St. Paul District. The Corps is soliciting public comments on the scope of the EA and significant issues that should be addressed. The Corps will also accept comments related to potential new ownership and management measures.

The Disposition Study ends when the final report is transmitted to the Corps of Engineers' Headquarters Office for review and processing of recommendations. Complete and partial de-authorization would require Congressional Approval.

Two public scoping meetings are planned as discussed in the **DATES** section above. The purpose of these meetings is to discuss background of the study, identify the properties and structures that are the subject of the study, discuss the Federal disposal process, instruct parties on how to document their interest in future ownership, provide an opportunity to submit comments, and identify issues that should be addressed in the anticipated EA. While comments and questions will be entertained at the public meetings, the meetings will not be recorded nor minutes prepared. All formal comments will be requested to be provided in writing. Written comments will be accepted at the meetings. Comments can also be submitted by the methods listed in the **ADDRESSES** section. Once the draft EA is complete and made available for review, there will be additional opportunity for public comment through the NEPA process.

Persons needing reasonable accommodations in order to attend and participate in the public scoping meetings should contact the person listed under the **FOR FURTHER INFORMATION CONTACT** section as soon as possible. In order to allow sufficient time to process requests, please make contact no later than one week before the public meeting.

Written comments, including email comments, should be sent to the Corps at the address given in the **ADDRESSES** section of this Notice. Comments should be specific and pertain only to the issues relating to the action and the anticipated EA. The Corps will include all comments in the project record.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information- will be publicly available. While you can ask us in your comment to withhold your personal identifying information from public review, the Corps 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 available for public review to the extent consistent with applicable law.

Dated: July 2, 2019.

Kari Hauck,

Acting Deputy Chief, Regional Planning and Environment Division North.

[FR Doc. 2019–15298 Filed 7–17–19; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Collier County Hurricane and Storm Damage Reduction Feasibility Study

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent/NEPA Scoping meeting and public comment period.

SUMMARY: In accordance with all applicable laws and regulations, the U.S. Army Corps of Engineers (USACE) plans to prepare a Feasibility Study with an integrated Environmental Impact Statement (EIS) to evaluate environmental impacts from reasonable project alternatives to protect nearshore areas of Collier County, Florida, from hurricanes and other storms with their associated wind, storm surge, and coastal flooding.

DATES: Scoping comments may be submitted until August 23, 2019.

ADDRESSES: The public is invited to submit NEPA scoping comments to Mr. David Schulte, Department of the Army, U.S. Army Corps of Engineers, Norfolk District, Fort Norfolk, 803 Front St., Norfolk, VA 23510 or via email: *David.M.Schulte@usace.army.mil.* The project title and the commenter's contact information should be included with submitted comments.

FOR FURTHER INFORMATION CONTACT: David Schulte, (757) 201–7007.

SUPPLEMENTARY INFORMATION: Applicable laws and regulations are section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4370, as implemented by the Council on Environmental Quality Regulations (40 CFR parts 1500–1508). The study authority is Section 4033 of the Water Resources Development Act of 2007 (Pub. L. 110–114), whereby the Secretary shall conduct a study to determine the feasibility of carrying out a project for hurricane and storm damage reduction and flood damage reduction in the vicinity of Vanderbilt, Park Shore, and Naples beaches, Collier County Florida. The primary problem is that existing protection is not adequate to prevent excessive storm damage and flooding from occurring during major coastal storms. Coastal flooding is worsening due to climate change induced sea level rise, which is also amplifying storm surge height. These trends are expected to continue and worsen due to sea level rise accelerating over time, a trend already observed in recent decades. Measures being considered include beach berms and dunes, floodwalls with gates, storm surge barriers, groins, seawalls, buyouts/elevations of buildings, wet and/or dry flood-proofing of buildings, and nature-based features potentially including mangrove restoration, oyster and/or coral reef restoration, and seagrass restoration.

USACE is the lead federal agency and Collier County will be the non-federal sponsor for the study. The Study/EIS will address the primary problem of the increasing storm damage and flooding occurring and expected to increase in the area by studying all reasonable alternatives and determine the Federal

interest in cost-sharing for those alternatives.

As required by Council on Environmental Quality's Principles, Requirements and Guidelines for Water and Land Related Resources Implementation Studies all reasonable alternatives to the proposed Federal action that meet the purpose and need will be considered in the EIS. These alternatives will include no action and a range of reasonable alternatives for protecting the shoreline and structures in Collier County, Florida.

Susan L. Conner,

Chief, Planning and Policy, Norfolk District USACE.

[FR Doc. 2019–15296 Filed 7–17–19; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Miami-Dade Back Bay Coastal Storm Risk Management Feasibility Study

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent/NEPA Scoping meeting and public comment period.

SUMMARY: In accordance with all applicable laws and regulations, the U.S. Army Corps of Engineers (USACE) plans to prepare a Feasibility Study with an integrated Environmental Impact Statement (EIS) to evaluate environmental impacts from reasonable project alternatives to protect low-lying and flood-prone areas of Miami-Dade County, Florida, from hurricanes and other coastal storms with their associated wind, storm surge, and coastal flooding.

DATES: Scoping comments may be submitted until August 23, 2019.

ADDRESSES: The public is invited to submit NEPA scoping comments to Ms. Carissa Agnese, Department of the Army, U.S. Army Corps of Engineers, Norfolk District, Fort Norfolk, 803 Front St., Norfolk, VA 23510 or via email: *Carissa.R.Agnese@usace.army.mil.* The project title and the commenter's contact information should be included with submitted comments.

FOR FURTHER INFORMATION CONTACT: Carissa Agnese, (757) 201–7752.

SUPPLEMENTARY INFORMATION: Applicable laws and regulations are section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4370, as implemented by the Council on Environmental Quality Regulations (40 CFR parts 1500–1508). The study authority is Public Law 84–71, which authorized the examination and survey of the coastal and tidal areas of the eastern and southern United States, with particular reference to areas where severe damages have occurred from hurricane winds and tides. The primary problem is that existing protection is not adequate to prevent excessive storm damage and flooding from occurring during major coastal storms. Coastal flooding is worsening due to climate change induced sea level rise, which is also amplifying storm surge height. These trends are expected to continue and worsen due to sea level rise accelerating over time, a trend already observed in recent decades. Measures being considered include ringwalls, floodwalls, storm surge barriers, buyouts/elevations of buildings, wet and/or dry flood-proofing of buildings, relocating structures and utilities, and nature-based features potentially including mangrove restoration, oyster and/or coral reef restoration, and seagrass restoration.

USACE is the lead federal agency and Miami-Dade County will be the non-federal sponsor for the study. The Study/EIS will address the primary problem of the increasing storm damage and flooding occurring and expected to increase in the area by studying all reasonable alternatives and determine the Federal interest in cost-sharing for those alternatives.

As required by Council on Environmental Quality's Principles, Requirements and Guidelines for Water and Land Related Resources Implementation Studies all reasonable alternatives to the proposed Federal action that meet the purpose and need will be considered in the EIS. These alternatives will include no action and a range of reasonable alternatives for protecting the shoreline and structures in Miami-Dade County, Florida.

Susan L. Conner,

Chief, Planning and Policy, Norfolk District USACE.

[FR Doc. 2019–15292 Filed 7–17–19; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of Navy

Notice of Intent To Grant a Partially Exclusive License; CHEMEON Surface Technology, LLC

AGENCY: Department of the Navy, DoD.

ACTION: Notice of intent to grant license.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to CHEMEON Surface Technology, LLC located at 2241 Park Place, Suite B, Minden, NV 89423, a revocable, nonassignable, partially exclusive license to practice the Government-Owned invention described in United States Patent Application number 15/474,374 titled ''Synergistic Metal Polycarboxylate Corrosion Inhibitors'' filed 30 March 2017 (PAX236); United States Patent Application number 16/184,264 titled ''Synergistic Metal Polycarboxylate Corrosion Inhibitors'' filed 08 November 2018 (PAX294); and United States Patent Application number 16/294,039 titled ''Synergistic Metal Polycarboxylate Corrosion Inhibitors'' filed 06 March 2019 (PAX315); and any divisional applications or continuation applications thereof, and any patents issuing from these applications, throughout the United States of America in the fields of use for CrVI and CrIII conversion coatings; phosphate conversion coatings; bluing; black oxide coatings on steel; and lubricants.

DATES: Anyone wishing to object to the grant of this license has fifteen (15) days from the publication date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with the Naval Air Warfare Center Aircraft Division, Technology Transfer Office, Attention Michelle Miedzinski, Code 5.0H, 22347 Cedar Point Road, Building 2185, Box 62, Room 2160, Patuxent River, Maryland 20670. File an electronic copy of objection with *michelle.miedzinski@navy.mil.*

FOR FURTHER INFORMATION CONTACT: Michelle Miedzinski, 301–342–1133, Naval Air Warfare Center Aircraft Division, 22347 Cedar Point Road, Building 2185, Box 62, Room 2160, Patuxent River, Maryland 20670, *michelle.miedzinski@navy.mil.*

Authority: (35 U.S.C. 207, 37 CFR part 404.)

Dated: July 15, 2019.

M.S. Werner,

Commander, Judge Advocate General's Corps, U. S. Navy, Federal Register Liaison Officer.

[FR Doc. 2019–15286 Filed 7–17–19; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–22–000]

Commission Information Collection Activities (FERC Form Nos. 1, 1–F, and 3–Q); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collections FERC Form Nos. 1 (Annual Report of Major Electric Utilities, Licensees, and Others), 1–F (Annual Report for Nonmajor Public Utilities and Licensees), and 3–Q (Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies), and submitting the information collections to the Office of Management and Budget (OMB) for review. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. On May 7, 2019, the Commission published a Notice in the **Federal Register** in Docket No. IC19–22–000 requesting public comments. The Commission received one public comment and will indicate that in its submittals to OMB.

DATES: Comments on the collections of information are due August 19, 2019.

ADDRESSES: Comments filed with OMB, identified by OMB Control Nos.: 1902–0021 (FERC Form No. 1), 1902–0029 (FERC Form No. 1–F), and 1902–0205 (FERC Form No. 3–Q) should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer.

A copy of the comments should also be sent to the Commission, in Docket No. IC19–22–000, by either of the following methods:

- *eFiling at Commission's website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Titles: FERC Form Nos. 1 (Annual Report of Major Electric Utilities, Licensees, and Others), 1–F (Annual Report for Nonmajor Public Utilities and Licensees), and 3–Q (Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies).

OMB Control Nos.: 1902–0021 (FERC Form No. 1), 1902–0029 (FERC Form No. 1–F), and 1902–0205 (FERC Form No. 3–Q).

Type of Request: Three-year extensions of the FERC Form Nos. 1, 1–F, and 3–Q with no changes to the current reporting and recordkeeping requirements.[1]

FERC Form No. 1, Annual Report of Major Electric Utilities, Licensees, and Others

Abstract: The FERC Form No. 1 is a comprehensive financial and operating report submitted annually for electric rate regulation, market oversight analysis, and financial audits by Major electric utilities, licensees and others. Major is defined as having in each of the last three consecutive calendar years, sales or transmission services that exceed one of the following: (1) One million megawatt-hours of total sales; (2) 100 megawatt-hours of sales for resale; (3) 500 megawatt-hours of power exchanges delivered; or (4) 500 megawatt-hours of wheeling for others (deliveries plus losses).[2]

The FERC Form No. 1 is designed to collect financial and operational information and is made available to the public. The FERC Form No. 1 includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Income,
- Statement of Retained Earnings,
- Statement of Cash Flows,
- Statements of Accumulated Comprehensive Income,
- Comprehensive Income, and Hedging Activities, and
- Notes to Financial Statements.

Supporting schedules contain:

- Supplementary information and outlines of corporate structure and governance,
- Information on formula rates, and
- Description of important changes during the year.

Other schedules provide:

- Information on revenues and the related quantities of electric sales and electricity transmitted,
- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data, and
- Other statistical information.

Type of Respondent: Major electric utilities.

Estimate of Annual Burden: [3] The Commission estimates the annual burden and cost [4] for FERC Form No. 1 as follows:

[1] FERC Form Nos. 1, 1–F, and 3–Q are part of the ''Forms Refresh'' effort, which is a separate activity and not addressed here. *See Revisions to the Filing Process for Commission Forms,* Order No. 859, 167 FERC ¶ 61,241 (2019) (started in Docket No. AD15–11 and ongoing in Docket No. RM19–12).

[2] As detailed in 18 CFR 101 (Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provision of the Federal Power Act, General Instructions) and 18 CFR 141.1.

[3] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1320.3.

[4] The Commission staff believes the FERC FTE (full-time equivalent) average cost for wages plus benefits is representative of the corresponding cost for the industry respondents. The FERC 2018 average salary plus benefits for one FERC FTE is $164,820/year (or $79.00/hour).

FERC FORM NO. 1

Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & average cost per response ($)	Total annual burden hours & total annual cost ($)	Cost per respondent ($)
(1)	(2)	(1) × (2) = (3)	(4)	(3) × (4) = (5)	(5) ÷ (1) = (6)
207	1	207	1,168 hrs.; $92,272	241,776 hrs.; $19,100,304	$92,272

FERC Form No. 1–F, Annual Report for Nonmajor Public Utilities and Licensees

OMB Control No.: 1902–0029.

Abstract: The FERC Form No. 1–F is a financial and operating report submitted annually for electric rate regulation, market oversight analysis, and financial audits by Nonmajor electric utilities and licensees. Nonmajor is defined as utilities and licensees that are not classified as Major, and having total sales in each of the last three consecutive years of 10,000 megawatt-hours or more.[5]

The FERC Form No.1–F is designed to collect financial and operational information and is made available to the public. The FERC Form No.1–F includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Retained Earnings,
- Statement of Cash Flows,
- Statement of Comprehensive Income and Hedging Activities, and
- Notes to Financial Statements.

Supporting schedules contain:

- Supplementary information and include revenues and the related quantities of electric sales and electricity transmitted,
- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data; and
- Other statistical information.

Type of Respondent: Nonmajor electric utilities.

Estimate of Annual Burden: The estimated annual burden and cost follow. (The estimated hourly cost used for the FERC Form No. 1–F is $79 (for wages plus benefits) and is described above, under the FERC Form No. 1.):

FERC FORM NO. 1–F

Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & average cost per response ($)	Total annual burden hours & total annual cost ($)	Cost per respondent ($)
(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
5	1	5	122 hrs.; $9,638	610 hrs.; $48,190	$9,638

Comments

One commenter, the Bureau of Economic Analysis (BEA), filed comments in response to the 60-day notice, broadly supporting the collection, outlining the manner in which BEA utilizes the FERC Form Nos. 1 and 1–F data, and expressing interest in additional data.[6] There were no comments filed in opposition to the collection.

BEA states that it uses FERC tabulations indirectly, as they are used to estimate the U.S. Census Bureau's Construction Value Put-In Place (VPIP) for electric utilities. BEA explains that Census VPIP serves a major source data input to the national income and product account (NIP A) structures investment estimates. According to BEA, NIPA estimates for electric structures rely upon the VPIP source data. As a result, BEA states that estimates of utility industry structures investment for the BEA Fixed Assets Accounts rely in turn upon the NIPA structures estimates and also directly upon selected Commission data sets published by the Energy Information Administration. BEA notes that while it uses this information indirectly through the VPIP program, BEA considers it an indispensable data source to the NIPA estimates.

BEA offers that it would like to explore receiving line items from Forms 1 and 1–F aggregated to industry totals, similar to the method and timing used to provide information to the Census Bureau. According to BEA, these tabulations would be used by BEA for, among other things, estimating industry gross output and changes in intermediate inputs. BEA explains that it would use the aggregated FERC data as well for the fixed asset account nonresidential structure investment, capital stock, and ultimately for consumption of fixed capital (depreciation) estimates that depend upon the NIPA structures estimates.

BEA states that it has in the past used items such as plant in service by type of utility; subsidiary and nonutility investments; allowance for funds used during construction; plant held for future use; plant leased to others; construction work in progress; depreciation; and other plant-related schedules because they are useful in estimating total industry plant-in-service. BEA further states that, in general, income statement and balance sheet data support utility industry investment by industry estimates. BEA notes that tabulations by legal form of ownership are also useful in the estimation of investment by legal form of organization for utility industries. BEA also expressed interest in plant-in-service separately identified for electric generation (by type of generation—hydro, nuclear, etc.), transmission, and distribution.

BEA requests that the Commission consider the inclusion of additional questions on the electric utility survey forms. Specifically, BEA suggests offering new questions that ask for capital expenditures for new versus replacement fixed assets, intangibles, and equipment and structures separately (excluding land). According to BEA, these questions would provide additional useful information to BEA that would lead to improved estimates

[5] As detailed in 18 CFR 101 (Uniform System of Accounts Prescribed for Public Utilities and Licensees Subject to the Provision of the Federal Power Act, General Instructions) and 18 CFR 141.2.

[6] The BEA comment is posted in FERC's eLibrary at *https://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=15275219.*

of capital spending at BEA and for Census/VPIP.

Finally, BEA offers that more detailed information about equipment and structures leased from others under operating leases would be useful for statistical purposes.

Commission Response

As discussed above, the public utilizes the data in FERC Form Nos. 1 and 1–F to assist in monitoring the rates, the financial condition of entities and in assessing energy markets. BEA's comments in support of the collection of the FERC Form Nos. 1 and 1–F data provide tangible examples of this utilization and reflect the public benefit of reporting this information. As further discussed above, the instant request to review and approve contains no changes to the reporting requirements for the existing information collections.

FERC Form No. 3–Q, Quarterly Financial Report of Electric Utilities, Licensees, and Natural Gas Companies

OMB Control No.: 1902–0205.

Abstract: The FERC Form No. 3–Q is a quarterly financial and operating report for rate regulation, market oversight analysis, and financial audits which supplements the (a) FERC Form Nos. 1 and 1–F, for the electric industry, or the (b) FERC Form No. 2 (Annual Report for Major Natural Gas Companies; OMB Control No. 1902–0028) and FERC Form No. 2–A (Annual Report for Nonmajor Natural Gas Companies; OMB Control No. 1902–0030), for the natural gas industry. The FERC Form No. 3–Q is submitted for all Major and Nonmajor electric utilities, licensees, and natural gas companies.[7]

FERC Form No. 3–Q includes a basic set of financial statements:

- Comparative Balance Sheet,
- Statement of Income and Statement of Retained Earnings,
- Statement of Cash Flows,
- Statement of Comprehensive Income and Hedging Activities, and
- Supporting schedules containing supplementary information.

Electric respondents report:

- Revenues and the related quantities of electric sales and electricity transmitted,
- Account balances for all electric operation and maintenance expenses,
- Selected plant cost data; and
- Other statistical information.

Natural gas respondents include:

- Monthly and quarterly quantities of gas transported and associated revenues,
- Storage, terminaling and processing services,
- Natural gas customer accounts and details of service, and
- Operational expenses, depreciation, depletion and amortization of gas plant.

Type of Respondent: Major and nonmajor electric utilities, licensees, and natural gas companies.

Estimate of Annual Burden: The estimated annual burden and cost (as rounded) follow. (The estimated hourly cost used for the FERC Form No. 3–Q is $79 (for wages plus benefits) and is described above, under the FERC Form No. 1.):

FERC Form No. 3–Q

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response	Total annual burden hours & total annual cost	Annual cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FERC 3–Q (electric)	212	3	636	168 hrs.; $13,272	106,848 hrs.; $8,440,992	$39,816
FERC 3–Q (natural gas)	165	3	495	167 hrs.; $13,193	82,665 hrs.; $6,530,535	39,579
Total for FERC 3–Q			1,131		189,513 hrs.; $14,971,527	

Comments: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 11, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–15294 Filed 7–17–19; 8:45 am]

BILLING CODE 6717–01–P

[7] 18 CFR 260.1(b) states that for natural gas companies as defined by the Natural Gas Act, Major pertains to a company whose combined gas transported or stored for a fee exceed 50 million Dth in each of the three previous calendar years. 18 CFR 260.2(b) states that for natural gas companies as defined by the Natural Gas Act, Nonmajor pertains to a company not meeting the filing threshold for FERC Form No. 2, but having total gas sales or volume transactions exceeding 200,000 Dth in each of the three previous calendar years.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–0269; FRL 9993–47–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Transportation Conformity Determinations for Federally Funded and Approved Transportation Plans, Programs and Projects (Reinstatement)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), Transportation Conformity Determinations for Federally Funded and Approved Transportation Plans, Programs, and Projects (EPA ICR Number 2130.06, OMB Control Number 2060–0561), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed reinstatement of the ICR, which was approved through March 31, 2019. Public comments were previously requested via the **Federal Register** on November 19, 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.

DATES: Additional comments may be submitted on or before August 19, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2007–0269, to (1) EPA online using *www.regulations.gov* (our preferred method) 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: Astrid Terry, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4812; email address: *terry.astrid@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 additional information about EPA's public docket, visit *www.epa.gov/dockets.*

Abstract: Transportation conformity is required under Clean Air Act section 176(c) (42 U.S.C. 7506(c)) to ensure that federally supported transportation activities are consistent with (conform to) the purpose of the State Air Quality Implementation Plan (SIP). Transportation activities include transportation plans, transportation improvement programs (TIPs), and federally funded or approved highway or transit projects. Conformity to the purpose of the SIP means that transportation activities will not cause or contribute to new air quality violations, worsen existing violations, or delay timely attainment of the relevant National Ambient Air Quality Standards (NAAQS)) or interim milestones.

Transportation conformity applies under EPA's conformity regulations at 40 CFR part 93, subpart A, to areas that are designated nonattainment and maintenance areas for the following transportation-related criteria pollutants: Ozone, particulate matter ($PM_{2.5}$ and PM_{10}), carbon monoxide (CO), and nitrogen dioxide (NO_2). EPA published the original transportation conformity rule on November 24, 1993 (58 FR 62188), and subsequently published several revisions. EPA develops the conformity regulations in coordination with the Federal Highway Administration (FHWA) and Federal Transit Administration (FTA). The federal government needs information collected under these regulations to ensure that metropolitan planning organization (MPO) and federal transportation actions are consistent with state air quality goals.

Form Numbers: None.

Respondents/affected entities: MPOs, local transit agencies, state departments of transportation, and state and local air quality agencies.

Respondent's obligation to respond: Mandatory pursuant to Clean Air Act section 176(c) (42 U.S.C. 7506(c)) and 40 CFR part 93.

Estimated number of respondents: 155.

Frequency of response: Typically, once every 4 years for transportation plans and TIPs, and for the largest MPOs with 3 or more NAAQS, once every 3 years for transportation plans and TIPs. As needed for projects.

Total estimated burden: 48,671 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,094,989 (per year), includes zero annualized capital or operation and maintenance costs.

Changes in estimates: There is a decrease of 11,877 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. A decrease in burden was projected due to the requirement for transportation conformity ending in PM_{10}, NO_2, and CO maintenance areas that have reached the end of the 20-year maintenance period. A decrease in burden was projected due to fewer transportation conformity determinations for areas previously designated nonattainment or maintenance for the 1997 $PM_{2.5}$ NAAQS. Burden was increased for the 1997 ozone NAAQS due to the *South Coast II* court decision, which occurred during the development of this ICR. The number of training hours was reduced for this ICR as no new emissions model has been released and additional hours for such a model transition and training are not anticipated. Based on the comments and supporting example documentation received during the first public comment period, EPA increased the estimated burden hours by 40% associated with an individual transportation plan and TIP conformity determination in the largest MPOs as well as increased TIP frequency for the largest MPOs where conformity applies for 3 or more NAAQS.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–15265 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9995–21–OMS]

Privacy Act of 1974; System of Records

AGENCY: Office of Mission Support, Environmental Protection Agency (EPA).

ACTION: Notice of a new system of records.

SUMMARY: The U.S. Environmental Protection Agency's (EPA) Office of the Administrator is giving notice that it proposes to create a new system of records pursuant to the provisions of the Privacy Act of 1974. iComplaints EEO Case Management System (ICOM) is being created to support the Agency's Employment Complaints Resolution program as required by the Equal Employment Opportunity Commission (EEOC) and in compliance with the requirements of the Code of Federal Regulations.

DATES: Persons wishing to comment on this system of records notice must do so by August 19, 2019. New routine uses for this modified system of records will be effective August 19, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OEI–2018–0219, by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.
- *Email: oei.docket@epa.gov.*
- *Fax:* (202) 566–1752.
- *Mail:* OEI Docket, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.
- *Hand Delivery:* OEI Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OEI–2018–0219. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at

www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov.* The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available (*e.g.,* CBI or other information for which disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1745.

FOR FURTHER INFORMATION CONTACT: Renee Clark, (202) 564–7272 or *clark.renee@epa.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Environmental Protection Agency (EPA) is creating a FedRAMP cloud service-based Privacy Act system of records for the processing of discrimination complaints. iComplaints (ICOM) is an information management and reporting system for internal EPA use. The information collected in the ICOM system is required by the Equal Employment Opportunity Commission (EEOC) under 29 CFR 1614.100 through 1614.110 and in order for the Agency to comply with EEOC Management Directive 110. Complainants provide their personally identifiable information (PII) to the EPA's Office of Civil Rights (OCR) so that they may be contacted in connection with the status of their complaint. ICOM will contain PII.

Only OCR EPA staff at Headquarters and in the Regions and the ICOM system contractors will have access to the database via approved computers logged on thru the EPA LAN network.

SYSTEM NAME AND NUMBER:

iComplaints EEO Case Management System (ICOM) EPA–80

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Civil Rights, US EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20004.

SYSTEM MANAGER(S):

Vicki Simons, Director, Office of Civil Rights, US EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20004, (202) 564–7272 or *simmons.vicki@epa.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 717 of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–16; Executive Order 11748; and Section 501 of the Rehabilitation Act of 1973, as amended by Public Law 99–506, 100 Stat. 1807, October 21, 1986, EEOC Management Directives 110 and 715.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the ICOM system is to maintain all EPA Equal Employment Opportunity discrimination complaints and subsequent reports, as required by the EEOC, in accordance with Title VII of the Civil Rights Act of 1964 (Title VII), as amended, 42 U.S.C. 2000e *et seq.,* 29 CFR 1614.101 through 1614.110 and EEOC Management Directive 110. The information collected will be used in complaint investigations, as required by the EEOC. The EEOC requires federal agencies to process complaints of discrimination raised by employees or applicants for employment. The documentation received for processing these complaints will contain personally identifiable information (PII) which will be housed in ICOM.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of the United States Environmental Protection Agency and applicants for employment.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains general human resources elements and contact information which includes Employee ID; Name; Home Address; Work Address; Email Address; Telephone Number; Series, Grade; Step, Salary; Target Grade; Management Level; Supervisor Level; Base Pay; Work Schedule; Fair Labor Standards Act; Union,; Position; Title; Sex; Disability; Age; Education Level; Academic Discipline; Veteran Status; Veteran preferences; Citizenship; Date Entered in Current Grade; Month-in-Grade; Service Completion Date; and Years-in-Service; Race; National Origin; Disability Status.

RECORD SOURCE CATEGORIES:

Employee, Supervisor or Applicant.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND PURPOSES OF SUCH USES:

The following new or modified routine uses apply to this system because the use of the record is necessary for the efficient conduct of government. The routine uses are related to and compatible with the original purpose for which the information was collected. The last two routine uses are required under OMB M–17–12.

(1) *Disclosure to Congressional Offices.*

Information may be disclosed to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

(2) *Disclosure to Contractors, Grantees, and Others.*

Information may be disclosed to contractors, grantees, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, job, or other activity for the Agency and who have a need to have access to the information in the performance of their duties or activities for the Agency. When appropriate, recipients will be required to comply with the requirements of the Privacy Act of 1974 as provided in 5 U.S.C. 552a(m).

(3) *Disclosures for Administrative Claims, Complaints and Appeals.*

Information from this system of records may be disclosed to an authorized appeal grievance examiner, formal complaints examiner, equal employment opportunity investigator,

arbitrator or other person properly engaged in investigation or settlement of an administrative grievance, complaint, claim, or appeal filed by an employee, but only to the extent that the information is relevant and necessary to the proceeding. Agencies that may obtain information under this routine use include, but are not limited to, the Office of Personnel Management, Office of Special Counsel, Merit Systems Protection Board, Federal Labor Relations Authority, Equal Employment Opportunity Commission, and Office of Government Ethics.

(4) *Disclosure in Connection with Litigation.*

Information from this system of records may be disclosed in connection with litigation or settlement discussions regarding claims by or against the Agency, including public filing with a court, to the extent that disclosure of the information is relevant and necessary to the litigation or discussions and except where court orders are otherwise required under section (b)(11) of the Privacy Act of 1974, 5 U.S.C. 552a(b)(11).

(5) *Disclosure to Persons or Entities in Response to an Actual of Suspected Breach of Personally Identifiable Information.*

To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that there has been a breach of the system of records, (2) the Agency has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(6) *Disclosure to assist another agency in its efforts to respond to a breach.*

To another Federal agency or Federal entity, when the Agency determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The paper records are maintained in locked file cabinets inside of a locked office located in the Office of Civil Rights, 1200 Pennsylvania Ave. NW, Washington, DC 20004. Users access the electronic records via the internet. All of the logic and processing functionality of ICOM resides on one or more central servers, with users accessing ICOM from Web browsers.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are retrieved by the individual's/employees' name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records stored in this system are subject to EPA records schedule number (EPA 0541).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

- Computer-stored information is protected in accordance with the Agency's security requirements.
- Access to the ICOM is limited to authorized and licensed users only. Access is granted via internet browser using uniquely assigned user identification and password. Only computers from approved IP addresses can access the database where ICOM records are stored. User access is granted in accordance with a role matrix that allows access to only those records necessary for approved Agency employee to conduct the necessary activities associated with processing an EEO complaint.
- The ICOM contractor is subject to the Federal Acquisition Regulations (FAR) Privacy Act clauses in its contract with EPA.
- ICOM servers are housed in a locked facility in a locked room requiring appropriate identification and biometrics to enter.
- Paper ICOM records are stored in locked file cabinets in a locked office. Only OCR staff with the appropriate security clearance and specific job function of processing EEO complaints has keys to access the paper records.

RECORD ACCESS PROCEDURE:

Individuals seeking access to information in this system of records about themselves are required to provide adequate identification (*e.g.,* driver's license, military identification card, employee badge or identification card). Additional identity verification procedures may be required, as warranted. Requests must meet the requirements of EPA regulations that implement the Privacy Act of 1974, at 40 CFR part 16.

CONTESTING RECORDS PROCEDURES:

Requests for correction or amendment must identify the record to be changed and the corrective action sought. Complete EPA Privacy Act procedures are described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURE:

Any individual who wants to know whether this system of records contains a record about him or her, who wants access to his or her record, or who wants to contest the contents of a record, should make a written request to the Attn: Agency Privacy Officer, MC 2831T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, *privacy@epa.gov.*

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Dated: June 5, 2019.

Vaughn Noga,

Senior Agency Official for Privacy.

[FR Doc. 2019–14468 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0659; FRL–9995–95–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Perchloroethylene Dry Cleaning Facilities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Perchloroethylene Dry Cleaning Facilities (EPA ICR Number 1415.12, OMB Control Number 2060–0234, 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 August 31, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 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 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 August 19, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0659, 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, EPA 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 Perchloroethylene Dry Cleaning Facilities (40 CFR part 63, subpart M) were proposed on December 9, 1991, promulgated on September 22, 1993, and most recently-amended on July 11, 2008. These regulations apply to existing and new dry-cleaning facilities that use perchloroethylene (PCE). New facilities include those that commenced either construction or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart M.

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, and are required of all affected facilities subject to NESHAP.

Form Numbers: None.

Respondents/affected entities: Dry cleaning facilities that use perchloroethylene.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart M).

Estimated number of respondents: 28,020 (total).

Frequency of response: Initially and occasionally.

Total estimated burden: 1,590,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $189,000,000 (per year), which includes $948,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The adjustment increase in burden from the most recently-approved ICR is due to an increase in the number of existing major sources. The EPA's records indicate that there are currently 20 major sources subject to this NESHAP; the previous estimate of 12 major sources was based on the final amendments to the NESHAP in 2008. There is also an adjustment increase in operation and maintenance costs due to the increase in the number of respondents. Finally, there is an adjustment increase in labor costs to account for costs from major source facilities operated by Federal employees versus the private sector.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–15264 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2015–0190; FRL–9996–46–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Nitric Acid Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Nitric Acid Plants (EPA ICR Number 1056.13, OMB Control Number 2060–0019), 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 September 30, 2019. Public comments were previously requested, via the **Federal Register**, on May 30, 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 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 August 19, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2015–0190, 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 New Source Performance Standards (NSPS) for Nitric Acid Plants (40 CFR part 60, subpart G) were proposed on August 17, 1971, promulgated on June 14, 1974, and amended on August 14, 2012. The NSPS for Nitric Acid Plants (40 CFR part 60, subpart Ga) were proposed on October 14, 2011, promulgated on August 14, 2012, and were amended on May 6, 2014 in order to correct a minor error. Subpart G applies to nitric acid production units, producing weak (30 to 70 percent) nitric acid, which commenced construction, modification or reconstruction either on or after August 17, 1971 and prior to October 14, 2011. Subpart G limits the emissions of nitrogen oxides, expressed as nitrogen dioxide (NO_2), to 1.5 kilograms per metric ton of acid produced (3.0 lb. per ton), and limits opacity to 10 percent. Subpart Ga applies to nitric acid production units, producing weak (30 to 70 percent) nitric acid, for which construction, reconstruction, or modification commenced after October 14, 2011, and limits nitrogen oxides (expressed as NO_2) to 0.50 lb per ton of 100 percent nitric acid produced. This information is being collected to assure compliance with 40 CFR part 60, subparts G and Ga.

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, and are required of all affected facilities subject to NSPS.

Form Numbers: None.

Respondents/affected entities: Nitric acid production units.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subparts G and Ga).

Estimated number of respondents: 32 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 2,530 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $3,040,000 (per year), which includes $2,750,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the cost estimates is due to adjustments for growth in the industry. There is an increase in the number of responses, labor hours, and operation and maintenance costs due to an increase in the number of respondents based on growth.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–15266 Filed 7–17–19; 8:45 am]

BILLING CODE 6560–50–P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy

Paperwork Reduction Act; Proposed Collection; Comment Request

AGENCY: Office of National Drug Control Policy.

ACTION: Notice of submission to OMB and 30-day public comment period. Reinstatement with change of previously approved collection: Drug-Free Communities (DFC) Support Program national evaluation.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Office of National Drug Control Policy (ONDCP) announces it will submit to the Office of Management and Budget (OMB) and Office of Information and Regulatory Affairs (OIRA) an information collection request. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: Public comments will be accepted until August 29, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the collection title by name or OMB Control Number, and should be sent to: Desk Officer for ONDCP, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Room 10235, New Executive Office Building, Washington, DC 20503 or electronically mailed to *oira_submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Helen Hernandez, Associate Director, Drug-Free Communities (DFC) Support Program. Email is the most reliable means of communication. Ms. Hernandez's email address is *HHernandez@ondcp.eop.gov*. Mailing address is: Executive Office of the President, Office of National Drug Control Policy, Drug-Free Communities (DFC) Support Program, 1800 G Street NW, Suite 9110, Washington, DC 20006. Copies of documents submitted to OMB and other information is available from Ms. Hernandez who may be contacted at 202–395–6665.

SUPPLEMENTARY INFORMATION: This notice informs the public that ONDCP has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published May 9, 2019, 84 FR 20357.

A. Overview of Information Collection

Title of Information Collection: Web-based data collection, surveys and interviews of Drug-Free Communities (DFC) Support Program and Community-Based Coalition Enhancement Grants to Address Local Drug Crisis (CARA Local Drug Crisis) Program grant award recipients.

Title: Drug-Free Communities (DFC) Support Program National Evaluation.

OMB Approval Number: 3201–0012.

Type of Request: Reinstatement with change of a previously approved collection.

Form Number: NA.

Description of the need for the information and proposed use: ONDCP administers the Drug-Free Communities (DFC) Support Program and Community-Based Coalition Enhancement Grants to Address Local Drug Crisis (CARA Local Drug Crisis) Programs. The DFC Program has two primary goals: To reduce youth substance abuse, and to support community anti-drug coalitions by establishing, strengthening, and fostering collaboration among public and private agencies. The CARA Local Drug Crisis grant program funds current or former DFC grant award recipients to focus on preventing and reducing the abuse of opioids or methamphetamines and the abuse of prescription medications among youth ages 12–18 in

communities throughout the United States.

Congress mandates an evaluation of the DFC program to determine its effectiveness in meeting objectives (see 21 U.S.C. 1521 *et al.*). Under the CARA Local Drug Crisis program statute, CARA Local Drug Crisis data collection is authorized and required by Public Law 114–198 Sec. 103, ''a grant under this section shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on the recipients of a grant under the Drug-Free Communities Act of 1997, and may also include an evaluation of the effectiveness at reducing abuse of opioids or methamphetamines''. ONDCP awarded a contract for a DFC grant oversight system at the end of 2014, following a competitive request for proposals process. The DFC Management and Evaluation (DFC *Me*) system was launched in 2016 and continues to be used (*www.dfcme.ondcp.eop.gov*). The development and implementation of the new DFC *Me* system provided an improved platform for DFC recipients to meet data reporting requirements of the grant, introduced a DFC Learning Center where resources and success stories can be shared, and strengthened ONDCP's continued oversight of the DFC program. The data collected through this system is more user friendly and validates data during entry, therefore reducing the burden on grant award recipients.

ONDCP will continue to utilize the case study protocols previously approved by OMB to document coalition practices, successes and challenges. Approximately nine DFC grant award recipients are selected each year to highlight in the case studies. The information from the case studies will be used to illustrate not only what works to reduce drug use in a community setting, but also how and why it works.

The CARA Local Drug Crisis program evaluation will make use of the monitoring and tracking questionnaire to serve as a semi-annual report for grant award recipients and will provide information to ONDCP and the Administration's effort to address the opioid crisis.

Respondents: DFC current grant award recipients and CARA Local Drug Crisis grant award recipients (includes both current and former DFC grant award recipients).

Estimated Number of Respondents: 737 (724 DFC and 13 CARA only).

Estimated Number of Responses: 2,181.

Frequency of Response: Semi-annually, annually and biennially. Progress reports semi-annually by DFC and CARA Local Drug Crisis Program Directors via DFC *Me,* core measures biennially by DFC and CARA Local Drug Crisis Program Directors via DFC *Me* and CCT annually for DFC Program Directors via DFC *Me.* Case study interviews of Program Directors and selected coalition members will be accomplished one time per site at nine sites.

Average Hours per Response: Varies. ONDCP expects that the time required for DFC grant award recipients to complete each semi-annual progress report will be approximately six hours, and each CCT report will take approximately one hour to complete. Face to face interviews and focus groups with DFC grant award recipients selected for site visits will take 1.5–2 hours each to complete. CARA Local Drug Crisis grant award recipients will also complete semi-annual progress reports at an estimated six hours. The estimate of time for DFC and CARA Local Drug Crisis grant award recipients includes biennial core measure data submission.

Total Estimated Burden: 9,388 (Comprehensive of all respondents over one year, including: DFC Program Directors and grant award recipients to complete progress reports, CCT surveys, and interviews; and CARA Local Drug Crisis grant award recipients.)

Solicitation of Public Comment

No comments were received during the 60-day notice. This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed data are proper for the functions of the agency;

(2) Whether the information will have practical utility;

(3) The accuracy of ONDCP's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;

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

ONDCP encourages interested parties to submit comments in response to these questions.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: July 15, 2019.

Michael Passante,

Deputy General Counsel.

[FR Doc. 2019–15303 Filed 7–17–19; 8:45 am]

BILLING CODE 3180–F5–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

TIME AND DATE: Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:41 a.m. on Tuesday, July 16, 2019, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

PLACE: The meeting was held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street, NW, Washington, DC.

STATUS: The meeting was closed to the public.

MATTERS CONSIDERED: In calling the meeting, the Board determined, on motion of Director Martin J. Gruenberg, seconded by Director Kathleen L. Kraninger (Director, Consumer Financial Protection Bureau), and concurred in by Joseph M. Otting (Comptroller of the Currency) and Chairman Jelena McWilliams, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B).

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated at Washington, DC, on July 16, 2019.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–15411 Filed 7–16–19; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE:
Tuesday, July 23, 2019 at 10:00 a.m. and its Continuation at The Conclusion of the Open Meeting on July 25, 2019.

PLACE:
1050 First Street NE, Washington, DC

STATUS:
This Meeting will be Closed to the Public.

MATTERS TO BE CONSIDERED:
Compliance matters pursuant to 52 U.S.C. 30109.

Matters relating to internal personnel decisions, or internal rules and practices.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION:
Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2019–15412 Filed 7–16–19; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Recordkeeping and Disclosure Requirements Associated with Regulation II (Debit Card Interchange Fees and Routing) (FR II OMB No. 7100–0349).

FOR FURTHER INFORMATION CONTACT:
Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA submission, supporting statements, and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Recordkeeping and Disclosure Requirements Associated with Regulation II (Debit Card Interchange Fees and Routing).

Agency form number: FR II.

OMB control number: 7100–0319.

Frequency: On occasion.

Respondents: State member banks, national banks, insured nonmember banks, savings associations, and federally-chartered credit unions.

Estimated number of respondents: Implement policies and procedures, 1 respondent; Review and update policies and procedures, 541 respondents; Annual notification and change in status, 541 respondents.

Estimated average hours per response: Implement policies and procedures, 160 hours; Review and update policies and procedures, 40 hours; Annual notification and change in status, 1 hour.

Estimated annual burden hours: Implement policies and procedures, 160 hours; Review and update policies and procedures, 21,640 hours; Annual notification and change in status, 541 hours.

General description of report: Regulation II, Debit Card Interchange Fees and Routing (12 CFR part 235), implements, among other things, standards for assessing whether interchange transaction fees for electronic debit transactions are reasonable and proportional to the cost incurred by the issuer with respect to the transaction, as required by section 920(a) of the Electronic Fund Transfer Act (EFTA) (15 U.S.C. 1693o–2(a)). Regulation II limits the interchange transaction fee that covered issuers can charge for debit card transactions. Under the rule a covered debit card issuer is allowed to receive or charge an amount of no more than 1 cent per transaction for the costs associated with preventing fraudulent electronic debit transactions (''fraud-prevention adjustment''), if the issuer complies with the standards and requirements set forth in the rule. In addition, issuers must retain records demonstrating their compliance with the requirements in Regulation II for at least five years after the end of the calendar year in which the electronic debit transaction occurred. Any person or issuer subject to an investigation or enforcement proceeding involving Regulation II must retain records pertaining to the matter until the final disposition of the matter, unless an earlier time is allowed by court or agency order.

Legal authorization and confidentiality: Section 920(a)(3) of the EFTA (15 U.S.C. 1693o–2(a)(3)), as added by section 1075 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, authorizes the Board to (1) prescribe regulations regarding interchange transaction fees that an issuer may charge with respect to electronic debit transactions, and to establish standards to assess whether the amount of any such fee is reasonable and proportional; and (2) require any issuer or payment card network to provide the Board such information as deemed necessary. Section 920(a)(5) of the EFTA (15 U.S.C. 1693o–2(a)(5)) further provides that the Board may allow for an adjustment to the interchange transaction fee amount received or charged by an issuer if ''(1) such adjustment is reasonably necessary to make allowance for costs incurred by the issuer in preventing fraud in relation to electronic debit card transactions involving that issuer; and (2) the issuer complies with the fraud-related standards established by the Board.'' Section 920(a)(5) also provides detailed requirements pertaining to the fraud-related standards to be established by the Board and authorizes the Board to promulgate such standards by rule. In addition, the EFTA (15 U.S.C. 1693o(a) and 1693o–2(d)) authorizes enforcement of compliance with the requirements implemented under the EFTA by the Board for entities that the Board has enforcement authority over under section 8 of the Federal Deposit Insurance Act (12 U.S.C. 1818), which covers member banks (other than national banks), branches and agencies

of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act (12 U.S.C. 601 *et seq*. and 611 *et seq*.).

Regulation II's fraud-prevention recordkeeping requirements (12 CFR 235.4(b)) and disclosure requirements (12 CFR 235.4(c) and (d)) are required in order for an issuer to obtain a benefit (*i.e.,* to be eligible to receive or charge the fraud-prevention adjustment). Regulation II's general recordkeeping requirements for issuers (12 CFR 235.8(c)) are mandatory. The records and notifications required under sections 235.4(b)–(d) and 235.8(c) of Regulation II are generally not submitted to the Board or the other federal financial regulatory agencies. Accordingly, normally no confidentiality issues arise under the Freedom of Information Act (FOIA) (5 U.S.C. 552). In the event such records or notifications are obtained by the Board through the examination or enforcement process, such information may be kept confidential under exemption 8 of the FOIA, which protects information contained in or related to the examination or supervision of a financial institution (5 U.S.C. 552(b)(8)).

Current actions: On April 8, 2019, the Board published a notice in the **Federal Register** (84 FR 13919) requesting public comment for 60 days on the extension, without revision, of the FR II. The comment period for this notice expired on June 7, 2019. The Board received two comments. After considering the comments received on the proposal, the Board will proceed with the extension, without revision, of the FR II.

Detailed Discussion of Public Comments

Comments were received from an individual and from a group of banking associations. The comment from the individual expressed support of the Dodd-Frank Act, and generally expressed opposition to any relaxation of rules implementing the Dodd-Frank Act. The comment from the group of banking associations supported the Board's proposal to maintain certain current recordkeeping processes while urging the Board to resist requests to reopen Regulation II to avoid further regulatory burden associated with the Durbin Amendment to the Dodd-Frank Act (if any such requests were received). The Board's recommended renewal, without revision, of the existing recordkeeping requirements is consistent with the views expressed in these comments.

Board of Governors of the Federal Reserve System, July 15, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–15313 Filed 7–17–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Semiannual Report of Derivatives Activity (FR 2436; OMB No. 7100–0286).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files. These documents also are available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Semiannual Report of Derivatives Activity.

Agency form number: FR 2436.

OMB control number: 7100–0286.

Frequency: Semiannually.

Respondents: Largest U.S. dealers of over-the-counter (OTC) derivatives.

Estimated number of respondents: 8.

Estimated average hours per response: 236.

Estimated annual burden hours: 3,776.

General description of report: Derivatives dealers provide data on outstanding positions (notional, gross positive, and gross negative fair values) with breakdowns by broad market risk category, product type, counterparty type, maturity, and specific underlying market risks—the currency, equity market, or reference entity that underlie the contract. In addition, reporters provide data on the credit exposures and liabilities arising from all outstanding credit default swaps contracts, as well as from the entire portfolio.

Legal authorization and confidentiality: This report is authorized under sections 2A and 12A of the Federal Reserve Act (FRA). Section 2A of the FRA requires the Federal Reserve Board and the Federal Open Market Committee (FOMC) to maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates (12 U.S.C. 225a). Section 12A of the FRA requires the FOMC to implement regulations relating to the open market operations conducted by Federal Reserve Banks with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country (12 U.S.C. 263). Because the Federal Reserve System uses the information obtained from the FR 2436 to fulfill these obligations, these statutory provisions provide the legal authorization for the collection of information on the FR 2436.

The FR 2436 is voluntary. Because the release of this information would cause substantial harm to the competitive position of the entity from whom the information was obtained, the information collected on the FR 2436 may be granted confidential treatment under exemption (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)),

which protects from disclosure ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.''

Current actions: On April 17, 2019, the Board published a notice in the **Federal Register** (84 FR 16015) requesting public comment for 60 days on the extension, without revision, of the FR 2436. The comment period for this notice expired on June 17, 2019. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, July 15, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–15312 Filed 7–17–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 12, 2019.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Senior Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *Banco Bradesco, S.A., Lecce Holdings S.A., Fundação Bradesco, BBD Participações S.A., Nova Cidade de Deus Participações S.A., and Cidade de Deus Cia. Comercial de Participações, all of Osasco, São Paulo, Brazil;* to become bank holding companies by acquiring substantially all of the shares of BAC Florida Bank, Coral Gables, Florida.

B. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Brodhead Bancshares, Inc., Brodhead, Wisconsin;* to acquire 100 percent of the voting shares of Farmers and Merchants Bank of Orfordville, Orfordville, Wisconsin.

Board of Governors of the Federal Reserve System, July 12, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–15250 Filed 7–17–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; ORR Data Collection for the Annual Survey of Refugees (OMB #0907–0033)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services (HHS) seeks an update to the existing data collection for the Annual Survey of Refugees. The Annual Survey of Refugees is a yearly sample survey of refugee households entering the U.S. in the previous five fiscal years. The requested update is based upon results of a multi-year effort in instrument redesign and field testing. ACF estimates the proposed changes will increase response burden from 30 to 45 minutes per respondent.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Data from the Annual Survey of Refugees are used to meet the Office of Refugee Resettlement's Congressional reporting requirements, as set forth in the Refugee Act of 1980 (Section 413(a) of the Immigration and Nationality Act). The Office of Refugee Resettlement makes survey findings available to the general public and uses findings for the purposes of program planning, policy-making, and budgeting.

The requested update reflects changes to the survey instrument to: Enhance ORR's understanding of refugees' resettlement experiences; streamline the collection of household-level information; and improve data reliability and validity.

Respondents: The Annual Survey of Refugees secures a nationally representative sample of refugee households arriving in the United States in the previous five fiscal years.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ORR–9 (Annual Survey of Refugees)	6000	2000	1	.75	1500
Pre-Survey Information Form	6000	2000	1	.05	100

Estimated Total Annual Burden Hours: 1,600

Comments: The Department specifically requests comments 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 of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 413. [8 U.S.C. 1523]

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–15274 Filed 7–17–19; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Emergency Use Authorization of Medical Products and Related Authorities

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 August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance: Emergency Use Authorization of Medical Products and Related Authorities

OMB Control Number 0910–0595—Extension

The guidance describes the Agency's policies applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b), as amended or added by the Project BioShield Act of 2004 (Pub. L. 108–276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), 21st Century Cures Act (Pub. L. 114–255), and Public Law 115–92 (2017). The FD&C Act permits the FDA Commissioner (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an emergency use authorization (EUA) must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the Commissioner may establish conditions on the authorization. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that he or she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to healthcare providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the FD&C Act also gives the Commissioner authority to establish other conditions on an authorization that he or she finds to be necessary or appropriate to protect the public health. Additionally, sections 564A and 564B established streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved products without requiring FDA to issue an EUA, including expiration date extension authority.

For purposes of estimating the annual burden of reporting (table 1), FDA has established four categories of respondents: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must

report to FDA regarding such activity; and (4) public health authorities (*e.g.,* State, local) who carry out an activity (*e.g.,* administering product, disseminating information) related to an unapproved EUA product who must report to FDA regarding such activity or who submit to FDA an expiration date extension request for an approved product.

In some cases, manufacturers directly submit EUA requests. Often a Federal Government entity (*e.g.,* Centers for Disease Control and Prevention, Department of Defense) requests that FDA issue an EUA and submits pre-EUA packages for FDA to review. In many of these cases, manufacturer respondents inform these requests and submissions, which are the activities that form the basis of the estimated reporting burdens. However, in some cases the Federal Government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the Federal Government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for ''original'' EUA and pre-EUA submissions than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (*i.e.,* estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities.

For purposes of estimating the annual burden of recordkeeping, FDA has also calculated the anticipated burden on manufacturers and public health officials associated with administration of unapproved products authorized for emergency use, recognizing that the Federal Government will perform much of the recordkeeping related to administration of such products (table 2). FDA is not calculating any recordkeeping burden for public health authorities who may need to submit expiration date extension requests, as these entities already maintain records for the products that they stockpile, which would include records of any expiration date request or extension.

The guidance refers to previously approved collections of information. These collections are subject to review by the OMB under the PRA. These collections have been approved as follows: Adverse experience reporting for biological products is approved under OMB control number 0910–0308; adverse drug experience reporting is approved under OMB control number 0910–0230; adverse device experience reporting is approved under OMB control number 0910–0471; investigational new drug (IND) application regulations are approved under OMB control number 0910–0014 and investigational device exemption (IDE) reporting is approved under OMB control number 0910–0078; current good manufacturing practices for finished pharmaceuticals are approved under OMB control number 0910–0139, and for devices under OMB control number 0910–0073; applications for marketing a new drug are approved under OMB control number 0910–0001, and for biological products under OMB control number 0910–0338. Any additional burden imposed by this proposed collection would be minimal.

In the **Federal Register** of April 4, 2019 (84 FR 13299), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	12	2.39	29	45	1,305
FDA Review of a Pre-EUA Package or an Amendment Thereto	32	1.79	57	34	1,938
Manufacturers of an Unapproved EUA Product	12	5.8	70	2	140
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Public Health Authorities; Request for Expiration Date Extension	1	1	1	2	2
Total					3,565

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	12	2	24	25	600
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					870

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the last OMB approval, our estimated annual reporting burden for the information collection reflects an increase due to an increase in the number of submissions we have received.

Dated: July 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15283 Filed 7–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4428]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application

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 August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0337. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill License Application—21 CFR Part 515

OMB Control Number 0910–0337—Extension

Feed manufacturers that seek to manufacture feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed, using Category I, Type A medicated articles that must follow proprietary formulas or specifications are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b). Our regulations in part 515 (21 CFR part 515) establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using Form FDA 3448 (§ 515.10(b) (21 CFR 515.10(b))). We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a pre-approval inspection.

We require the submission of a supplemental medicated feed mill license application for a change in facility ownership or a change in facility address (§ 515.11(b) (21 CFR 515.11(b))). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23 (21 CFR 515.23), a manufacturer may request voluntary revocation of a medicated feed mill license. An applicant also has the right to file a request for hearing under § 515.30(c) (21 CFR 515.30(c)) to give reasons why a medicated feed mill license should not be refused or revoked.

In the **Federal Register** of December 26, 2018 (83 FR 66280), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated Feed Mill License Application using Form FDA 3448 (515.10(b)).	14	1	14	0.25 (15 minutes)	4
Supplemental Feed Mill License Application using Form FDA 3448 (515.11(b)).	54	1	54	0.25 (15 minutes)	14
Voluntary Revocation of Medicated Feed Mill License (515.23).	29	1	29	0.25 (15 minutes)	7
Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c)).	1	1	1	4	4
Total					29

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Feed (510.305).	837	1	837	0.03 (2 minutes)	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on our experience with medicated feed mill license applications. We estimate that we will receive 14 medicated feed mill license applications, 54 supplemental applications, 29 requests for voluntary revocation, and that these submissions will take approximately 15 minutes per response, as shown in table 1, rows 1 through 3. We estimate that preparing a request for a hearing under § 515.30(c) takes approximately 4 hours, as shown in table 1, row 4. In table 2, we estimate that 837 licensees will keep the records required by 21 CFR 510.305, expending a total of 25 hours annually.

Our estimated burden for the information collection reflects an overall decrease of 2 hours and a corresponding decrease of 56 responses/records. We attribute this adjustment to a net decrease in the number of submissions we received over the last few years.

Dated: July 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15284 Filed 7–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0893]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Devices and Radiological Health Appeals Processes

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 August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0738. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910–0738—Extension

The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes'' [1] describes the processes available to outside stakeholders to request additional review of decisions or actions by Center for Devices and Radiological Health (CDRH) employees. FDA is seeking approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees as described in the guidance.

Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. Of these, by far the most commonly used is a request for supervisory review under § 10.75 (21 CFR 10.75) (''10.75 appeal''). Section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360g–1), added by section 603 of the Food and Drug Administration Safety and Innovation Act, includes requirements pertaining to the process and timelines for 10.75 appeals of ''significant decisions'' regarding 510(k) premarket notifications, applications for premarket approvals (PMAs), and applications for investigational device exemptions (IDEs).

A request for review under § 10.75 should be based on the information that was already present in the administrative file at the time of the decision that is being reviewed as provided in § 10.75(d). Section 517A of the FD&C Act refers to significant decisions regarding the information in the administrative file for premarket notification (section 510(k) of the FD&C Act (21 U.S.C. 360(k))), PMA (section 515 (21 U.S.C. 360e)), and IDE (section 520(g) (21 U.S.C. 360j(g))) submissions that is collected under existing regulations that specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of medical devices. The information collections associated with these regulations are currently approved by the OMB as follows: The collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078.

While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the decision under review. The guidance describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information.

In the **Federal Register** of March 8, 2019 (84 FR 8530), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

[1] *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284670.pdf.*

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
CDRH Appeals Processes Guidance Document	35	1	35	8	280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects a decrease of 15 responses and a corresponding overall decrease of 120 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: July 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15270 Filed 7–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2808]

Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' This draft guidance describes the FDA's current recommendations regarding the overall development program and clinical trial designs for developing gonadotropin-releasing hormone (GnRH) analogues to treat advanced prostate cancer.

DATES: Submit either electronic or written comments on the draft guidance by September 16, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–2808 for ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 22, Rm. 2169, Silver Spring, MD 20993–0002, 240–402–2628.

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' This draft guidance describes the FDA's current recommendations regarding the overall development program and clinical trial designs for developing GnRH analogues to treat advanced prostate cancer.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (''Protection of Human Subjects: Informed Consent; Institutional Review Boards'') have been approved under OMB control number 0910–0755. The collections of information in 21 CFR parts 201.56 and 201.57 (Prescription Drug Labeling) have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: July 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15268 Filed 7–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Inspection by Accredited Persons Program

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 August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0510. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St. North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria

OMB Control Number 0910–0510—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA added a new paragraph (g) to section 704 of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. FDA's guidance document entitled ''Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria'' [1] provides information for those interested in participating in this voluntary program.

In the **Federal Register** of March 14, 2019 (84 FR 9352), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act; Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
704(g); Request for Accreditation	1	1	1	80	80

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[1] *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm089721.pdf.*

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15269 Filed 7–17–19; 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: The National Health Service Corps Loan Repayment Program, OMB No. 0915–0127—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

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 should be received no later than September 16, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail them to 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: The National Health Service Corps Loan Repayment Program, OMB No. 0915–0127—Revision.

Abstract: The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. The NHSC Substance Use Disorder (SUD) Workforce LRP and the NHSC Rural Community LRP were established to recruit and retain a health professional workforce with specific training and credentials to provide evidence-based SUD treatment in HPSAs. Under these programs, HHS agrees to repay the qualifying educational loans of selected primary care health professionals. In return, the health professionals agree to serve for a specified period of time in a NHSC-approved site located in a federally-designated HPSA approved by the Secretary for LRP participants. The forms utilized by each LRP include the following: (1) The NHSC LRP Application, the Authorization for Disclosure of Loan Information form, (2) the Privacy Act Release Authorization form, and, if applicable, (3) the Verification of Disadvantaged Background form, and (4) the Private Practice Option form. The first three of the aforementioned NHSC LRP forms collect information that is needed for selecting participants and repaying qualifying educational loans. The last referenced form, the Private Practice Option Form, is needed to collect information for all participants who have applied for that service option.

NHSC-approved sites are health care facilities that provide comprehensive outpatient, ambulatory, primary health care services to populations residing in HPSAs. Related in-patient services may be provided by NHSC-approved Critical Access Hospitals and Indian Health Service hospitals. In order to become an NHSC-approved site, new sites must submit a Site Application for review and approval. Existing NHSC-approved sites are required to complete a Site Recertification Application every 3 years in order to maintain their NHSC-approved status. Both the NHSC Site Application and Site Recertification Application request information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing these applications may be obtained through the appropriate State Primary Care Office and the NHSC. The information collected on the applications is used for determining the eligibility of sites for the assignment of NHSC health professionals and to verify the need for NHSC clinicians. NHSC service site approval is valid for 3 years.

Need and Proposed Use of the Information: The need and purpose of this information collection is to assess an LRP applicant's eligibility and qualifications for the LRP, and to obtain information for NHSC site applicants. The NHSC LRP application asks for personal, professional, and financial/loan information.

The proposed revisions in this ICR include asking applicants to provide their educational information on the completion of advanced training such as the Primary Care Training and Enhancement (PCTE) Champion fellowship. To identify the PCTE Champions, the NHSC will require applicants to respond to the following additional questions and submit their National Practitioner Identifier (NPI):

(1) Have you completed a fellowship?

(2) Applicants who selected ''yes'' to the question above are required to submit the NPI number.

NHSC policy requires behavioral health providers to practice in a community-based setting that provides access to comprehensive behavioral health services. Accordingly, for those sites seeking to be assigned behavioral health NHSC participants, additional site information will be collected from an NHSC Comprehensive Behavioral Health Services Checklist. NHSC sites that do not directly offer all required behavioral health services must demonstrate a formal affiliation with a comprehensive, community-based primary behavioral health setting or facility to provide these services.

Likely Respondents: Likely respondents include: (1) Licensed primary care medical, dental, and mental and behavioral health providers who are employed or seeking employment, and are interested in serving underserved populations; (2) health care facilities interested in participating in the NHSC and becoming an NHSC-approved service site; and (3) NHSC sites providing behavioral health care services directly, or through a formal affiliation with a comprehensive community-based primary behavioral health setting or facility providing comprehensive behavioral health services.

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 name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC LRP Application	9,020	1	9,020	1.00	9,020.0
Authorization for Disclosure of Loan Information Form	7,150	1	7,150	.10	715.0
Privacy Act Release Authorization Form	303	1	303	.10	30.3
Verification of Disadvantaged Background Form	660	1	660	.50	330.0
Private Practice Option Form	330	1	330	.10	33.0
NHSC Comprehensive Behavioral Health Services Checklist	4,400	1	4,400	.13	572.0
NHSC Site Application (including recertification)	4,070	1	4,070	.50	2,035.0
Total	25,933		25,933		12,735.3

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.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–15306 Filed 7–17–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html*.

DATES: The meeting will be held on Tuesday, July 30, 2019, from 9 a.m. until 4:45 p.m., and Wednesday, July 31, 2019, from 9 a.m. until 3:30 p.m.

ADDRESSES: National Institutes of Health, Vaccine Research Center Rooms 1201/1203, 40 Convent Drive, Bethesda, Maryland 20892.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification or coordination.

The SACHRP meeting will open to the public at 9 a.m., on Tuesday, July 30, 2019, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair. New SACHRP members will be welcomed and introduced.

The SOH subcommittee will present its recommendations on End User Licensing Agreements and Terms of Service, and Charging Subjects to Participate in Clinical Trials. This will be followed by a discussion of site monitoring under single IRB review, with a review of possible recommendations, and finally a discussion of guidance for institutions affected by the end of the voluntary check-the-box option to extend a federalwide assurance to all research regardless of funding.

Wednesday will begin with a discussion of questions newly posed to SACHRP regarding Deceased Organ Intervention Research (DDIR), with a particular focus on recipient informed consent. There will be a panel presentations from leading experts in the field of DDIR, followed by SACHRP discussion. This will be followed by a discussion of ethical and regulatory issues surrounding reconsent of subjects for human subjects research. The meeting is scheduled to end at approximately 3:30 p.m.

Time will be allotted for public comment on both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to topics currently being addressed by the SACHRP. Individuals submitting written statements as public comment should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special

assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated SACHRP point of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: July 3, 2019.

Julia G. Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2019–15289 Filed 7–17–19; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2019–0005; OMB No. 1660–0024]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Federal Assistance for Offsite Radiological Emergency Preparedness and Planning

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before August 19, 2019.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov,* Renae Connell, Emergency Management Specialist, FEMA/NPD/THD, *renae.connell@fema.dhs.gov,* 202–657–2294, or Darrell Givens, Emergency Management Specialist, FEMA/NPD/THD, *darrell.givens@fema.dhs.gov,* 202–212–7854.

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on April 24, 2019 at 84 FR 17182 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Federal Assistance for Offsite Radiological Emergency Preparedness and Planning.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0024.

Form Titles and Numbers: There are no forms for this collection; rather the regulatory text details the content in which information is transmitted to FEMA.

Abstract: The intent of this request is the collection of comments on an extension, without change, of a currently approved information collection an OMB control number representing all information collections related to FEMA Radiological Emergency Preparedness Program requirements described in 44 CFR parts 350 and 352.

Affected Public: State, Local or Tribal Government; and business and other for profits.

Estimated Number of Respondents: 153.

Estimated Number of Responses: 153.

Estimated Total Annual Burden Hours: 5,360.

Estimated Total Annual Respondent Cost: $311,458.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $566,163.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2019–15230 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4441–DR; Docket ID FEMA–2019–0001]

Arkansas; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Arkansas (FEMA–4441–DR), dated June 8, 2019, and related determinations.

DATES: This amendment was issued July 3, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Arkansas is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 8, 2019.

Lincoln County for Individual Assistance (already designated for emergency protective measures [Category B], limited to direct federal assistance under the Public assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15244 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4393–DR; Docket ID FEMA–2019–0001]

North Carolina; Amendment No. 12 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 State of North Carolina (FEMA–4393–DR), dated September 14, 2018, and related determinations.

DATES: This change occurred on June 27, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472 (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Elizabeth Turner, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Nancy Casper as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15232 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4421–DR; Docket ID FEMA–2019–0001]

Iowa; Amendment No. 13 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA–4421–DR), dated March 23, 2019, and related determinations.

DATES: This amendment was issued July 9, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa 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 March 23, 2019.

Muscatine 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.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15235 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4421–DR; Docket ID FEMA–2019–0001]

Iowa; Amendment No. 12 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA–4421–DR), dated March 23, 2019, and related determinations.

DATES: This amendment was issued July 2, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472 (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of March 23, 2019.

Floyd, Keokuk, and Wapello Counties for Public Assistance

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15237 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4447–DR; Docket ID FEMA–2019–0001]

Ohio; Amendment No. 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 Ohio (FEMA–4447–DR), dated June 18, 2019, and related determinations.

DATES: This amendment was issued July 2, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Ohio is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 18, 2019.

Mahoning County for Individual Assistance

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15243 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4420–DR; Docket ID FEMA–2019–0001]

Nebraska; Amendment No. 8 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 Nebraska (FEMA–4420–DR), dated March 21, 2019, and related determinations.

DATES: This amendment was issued June 28, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Nebraska is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of March 21, 2019.

Cherry, Nuckolls, and Scotts Bluff Counties and the Omaha Tribe of Nebraska, Sac and Fox Nation of Missouri in Kansas and Nebraska, Santee Sioux Nation, and the Winnebago Tribe of Nebraska within the designated counties for Public Assistance [Categories C–G] (already designated 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.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15234 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4441–DR; Docket ID FEMA–2019–0001]

Arkansas; Amendment No. 3 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 Arkansas (FEMA–4441–DR), dated June 8, 2019, and related determinations.

DATES: This amendment was issued July 3, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Arkansas is hereby amended to include permanent work under the Public Assistance program for those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 8, 2019.

Conway, Crawford, Faulkner, Jefferson, Perry, Pulaski, Sebastian, and Yell 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).

Desha and Logan Counties for Public Assistance [Categories A–G] (already designated for Individual Assistance and emergency protective measures [Category B], limited to direct federal assistance, under the Public Assistance program).

Franklin County for Public Assistance [Categories A–G] (already designated for emergency protective measures [Category B], limited to direct federal assistance, under the Public Assistance program).

Searcy County for Public Assistance [Categories A–G], including direct federal assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals

and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15240 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4412–DR; Docket ID FEMA–2019–0001]

North Carolina; 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 State of North Carolina (FEMA–4412–DR), dated January 31, 2019, and related determinations.

DATES: This change occurred on June 27, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472 (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Elizabeth Turner, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Nancy Casper as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15233 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4440–DR; Docket ID FEMA–2019–0001]

South Dakota; 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 South Dakota (FEMA–4440–DR), dated June 7, 2019, and related determinations.

DATES: This amendment was issued June 24, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of South Dakota is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 7, 2019.

Turner County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15239 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4434–DR; Docket ID FEMA–2019–0001]

California; 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 California (FEMA–4434–DR), dated May 17, 2019, and related determinations.

DATES: This amendment was issued June 24, 2019.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California 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 May 17, 2019.

Yolo County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Acting Administrator, Federal Emergency Management Agency.

[FR Doc. 2019–15236 Filed 7–17–19; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000.L63100000.HD0000. 19XL1116AF.HAG 19–0109]

Filing of Plats of Survey: Oregon/ Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management (BLM), Oregon State Office, Portland, Oregon, 30 calendar days from the date of this publication.

DATES: Protests must be received by the BLM prior to the scheduled date of official filing, August 19, 2019.

ADDRESSES: A copy of the plats may be obtained from the public room at the Bureau of Land Management, Oregon State Office, 1220 SW 3rd Avenue, Portland, Oregon 97204, upon required payment. The plats may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, 503–808–6124, Branch of Geographic Sciences, Bureau of Land Management, 1220 SW 3rd Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact the above individual during normal business hours. The service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon:

WILLAMETTE MERIDIAN, OREGON

T. 18 S., R. 37 E., accepted June 11, 2019

WILLAMETTE MERIDIAN, WASHINGTON

T. 30 N., R. 5 E., accepted May 23, 2019
T. 31 N., R. 15 W., accepted July 3, 2019

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the Chief Cadastral Surveyor for Oregon/ Washington, Bureau of Land Management. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be filed before the scheduled date of official filing for the plat(s) of survey being protested. Any notice of protest filed after the scheduled date of official filing will be untimely and will not be considered. A notice of protest is considered filed on the date it is received by the Chief Cadastral Surveyor for Oregon/ Washington during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the Chief Cadastral Surveyor for Oregon/ Washington within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day following the resolution of all protests of the plat. Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Mary J.M. Hartel,

Chief Cadastral Surveyor of Oregon/ Washington.

[FR Doc. 2019–15314 Filed 7–17–19; 8:45 am]

BILLING CODE 4310–33–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1424 (Final)]

Mattresses From China; Revised Schedule for the Subject Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: July 8, 2019.

FOR FURTHER INFORMATION CONTACT: Calvin Chang (202–205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On May 28, 2019, the Commission established a schedule for the conduct of the final phase of the subject investigation (84 FR 27657, June 13, 2019). The Commission is revising its schedule by changing the hearing date.

The Commission's revised schedule is as follows: Requests to appear at the hearing must be filed with the Secretary to the Commission not later than October 8, 2019; the prehearing conference will be held at the U.S. International Trade Commission Building on October 10, 2019, if deemed necessary; the prehearing staff report will be placed in the nonpublic record on September 19, 2019; the deadline for filing prehearing briefs is September 26, 2019; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on October 15, 2019; the deadline for filing posthearing briefs is October 22, 2019; the Commission will make its final release of information on November 12, 2019; and final party comments are due on November 14, 2019.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: July 12, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–15217 Filed 7–17–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1114 (Second Review)]

Steel Nails From China

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on steel nails from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted this review on December 3, 2018 (83 FR 62342, December 3, 2018) and determined on April 12, 2019 that it would conduct an expedited review (84 FR 26445, June 6, 2019).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on July 12, 2019. The views of the Commission are contained in USITC Publication 4920 (July 2019), entitled *Steel Nails from China: Investigation No. 731–TA–1114 (Second Review).*

By order of the Commission.

Issued: July 12, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–15219 Filed 7–17–19; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

NATIONAL SCIENCE FOUNDATION

Request for Information on VIA Task Force Report: R&D Opportunities in Video & Image Analytics

AGENCY: Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation (NSF).

ACTION: Notice of Request for Information (RFI).

SUMMARY: On behalf the National Science and Technology Council (NSTC) Committee on Science & Technology Enterprise, NITRD NCO requests input from all interested parties on the VIA Task Force Report: R&D Opportunities in Video & Image Analytics including from those working on Artificial Intelligence (AI) and/or VIA research and development (R&D). Responses to this Request for Information (RFI) can be general suggestions of revisions or improvements to the VIA Task Force Report, comments on the six strategic goals and objectives, and suggestions to the implementation of the strategic goals and objectives. The public input provided in response to this RFI will inform NITRD NCO, and the VIA Task Force on developing the VIA Task Force Report: R&D Opportunities in Video & Image Analytics.

DATES: Interested persons are invited to submit comments on or before 11:59 p.m. (ET) on August 31, 2019.

ADDRESSES: Comments submitted in response to this notice may be sent by any of the following methods:

- *Email: VIA-RFI@nitrd.gov.* Email submissions should be machine-readable and not be copy-protected. Submissions should include ''RFI Response: R&D Opportunities in Video & Image Analytics'' in the subject line of the message.
- *Fax:* (202) 459–9673, Attn: Alex Thai; or
- *Mail:* Attn: Alex Thai, NITRD NCO, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA.

Instructions: Response to this RFI is voluntary. Each individual or institution is requested to submit only one response. Submissions must not exceed 10 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) filing the comment.

Please note, responses to this RFI may be posted for public access online at *http://www.nitrd.gov.* Therefore, we request that no business proprietary information, copyrighted information, personally identifiable information, or personal signatures 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 Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT: Alex Thai at (202) 459–9674 or *VIA-RFI@nitrd.gov,* or by post mailing to 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:

Background: Past Federal research in VIA has resulted in innovative research and effective agency-specific capabilities. These investments, along with technology advancements and cost reductions, have given rise to an abundance of technologies for both government and commercial markets. More importantly, these investments have provided foundational expertise in computer vision and machine learning and dramatically increased research in video analytics across government and industry. Looking forward, thirty Federal organizations came together under the auspices of the NITRD VIA Task Force to map the future and develop this report, which is intended to provide direction, coherence and consensus for future Federal R&D efforts. There are gaps in research investment that, while critical for Federal agencies, are unlikely to receive enough investment by industry. The VIA Task Force seeks the following input from the community:

(1) Are the goals, objectives, and recommendations stated in this report achievable? If not, please explain.

(2) This report focuses on Federal government areas of need where industry is unlikely to pursue solutions. Are there plans from industry that are not reflected in this report and could result in unintended duplication?

(3) How do state and local government's interests align with the Federal government's vision?

(4) Are there gaps in VIA R&D that the Federal government should consider pursuing?

(5) Please provide any general feedback on the VIA Task Force Report.

Reference: The VIA Task Force Report: R&D Opportunities in Video & Image Analytics: *https://www.nitrd.gov/drafts/DRAFT-VIA-TF-Report-RD-Opportunities-2019.pdf.* Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on July 15, 2019.

(Authority: 42 U.S.C. 1861.)

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–15315 Filed 7–17–19; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–461; NRC–2019–0107]

Exelon Generation Company LLC; Clinton Power Station Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a November 8, 2018, request from Exelon Generation Company, LLC (Exelon) to allow Exelon to submit a sufficient license renewal application for Clinton Power Station, Unit 1, at least 3 years prior to the expiration of the existing license and still receive timely renewal protection.

DATES: The exemption was issued on July 11, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0107 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2019–0107. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (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: Joel S. Wiebe, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6606, email: *Joel.Wiebe@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated at Rockville, Maryland, this 15th day of July, 2019.

For the Nuclear Regulatory Commission.

Joel S. Wiebe,

Senior Project Manager, Licensing Projects Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

ATTACHMENT—Exemption

NUCLEAR REGULATORY COMMISSION

Docket No. 50–461

Exelon Generation Company, LLC

Clinton Power Station, Unit 1

Exemption

I. Background

Exelon Generation Company, LLC (Exelon, the licensee), holds Facility Operating License No. NPF–62, which authorizes operation of the Clinton Power Station, Unit 1 (CPS), a boiling-water reactor facility, located in Dewitt County, Illinois. The license, among other things, subjects the facility to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect. The current operating license for CPS expires on April 17, 2027.

By letter dated November 8, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18312A139), Exelon requested an exemption to allow Exelon to submit a license renewal application for CPS at least 3 years prior to the expiration of the existing license and, if found to be sufficient by the NRC, still receive timely renewal protection under Title 10 of the *Code of Federal Regulations* (10 CFR), Part 2, Section 2.109(b). 10 CFR 2.109(b) provides timely renewal protection to licensees that submit sufficient license renewal applications at least 5 years before the expiration of the existing license. In its application, Exelon informed the NRC that the economic viability of continued operation of CPS beyond the current expiration date of its NRC license is uncertain. According to Exelon, due to continuing and significant changes in the economic and legislative environments that materially affect continued CPS operation, Exelon will not be in a position to make a reasonable and sound business decision 5 years prior to the expiration of the CPS license as to whether to pursue license renewal. Exelon contends that allowing it to make that decision at a later date, when the economic viability of extended CPS operation can be more readily assessed, will result in more efficient use of both Exelon and NRC financial and other resources.

II. Request/Action

10 CFR 54.17(a) requires that an application for a renewed license be in accordance with Subpart A of 10 CFR, Part 2, which includes 10 CFR 2.109(b). In turn, 10 CFR 2.109(b) states, ''If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 50.22 files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.'' In its letter dated November 8, 2018, Exelon requested an exemption from 10 CFR 54.17(a) to allow Exelon to submit its license renewal application for CPS at least 3 years prior to the expiration of the existing license and still receive timely renewal protection under 2.109(b). 10 CFR 54.15 allows exemptions from the requirements of Part 54 in accordance with 10 CFR 50.12.

III. Discussion

Under 10 CFR 54.15, exemptions from the requirements of Part 54 are governed by 10 CFR 50.12. Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present, as defined in 10 CFR 50.12(a)(2). In its application, Exelon stated that three special circumstances apply to its request: 10 CFR 50.12(a)(2)(ii), ''[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule;'' 10 CFR 50.12(a)(2)(iii), ''[c]ompliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated;'' and 10 CFR 50.12(a)(2)(vi), other material circumstances not considered when the regulation was adopted are present, such that granting the exemption is in the public interest.

A. The Exemption Is Authorized by Law

This exemption would allow Exelon to submit a license renewal application for CPS at least 3 years prior to the expiration of its existing license and, if sufficient, still receive timely renewal protection under 10 CFR 2.109(b). 10 CFR 2.109 implements Section 9(b) of the Administrative Procedure Act (APA), 5 U.S.C. 558(c), which states:

> When the licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.

The 5-year time period specified in 10 CFR 2.109 is the result of a discretionary agency rulemaking and not required by the APA. As stated above, 10 CFR 54.15 allows the NRC to grant exemptions from the requirements of 10 CFR part 54. The NRC has determined that granting this exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, the APA, or the NRC's regulations. Therefore, the exemption is authorized by law.

B. The Exemption Presents no Undue Risk to Public Health and Safety

The requested exemption to allow a 3-year time period, rather than the 5 years specified in 10 CFR 2.109(b), for Exelon to submit a sufficient license renewal application and receive timely renewal protection is a scheduling change. The action does not change the manner in which the plant operates and maintains public health and safety because no additional changes are made as a result of the action. The NRC expects that a period of 3 years provides sufficient time for the NRC to perform a full and adequate safety and environmental review, and for the completion of the hearing process. Pending final action on the license renewal application, the NRC will continue to conduct all regulatory activities associated with licensing, inspection, and oversight, and will take whatever action may be necessary to ensure adequate protection of the public health and safety. The existence of this exemption does not affect NRC's authority, applicable to all licenses, to modify, suspend, or revoke a license for cause, such as a serious safety concern. Based on the above, the NRC finds that the action does not cause undue risk to public health and safety.

C. The Exemption Is Consistent With the Common Defense and Security

The requested exemption to allow for a timely renewal protection deadline of at least 3 years instead of 5 years is a scheduling change. The exemption does not change any site security matters. Therefore, the NRC finds that the action is consistent with the common defense and security.

D. Special Circumstances

The purpose of 10 CFR 2.109(b), as it is applied to nuclear power reactors licensed by the NRC, is to implement the ''timely renewal'' provision of Section 9(b) of the APA, 5 U.S.C. 558(c), which states:

> When the licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency.

The underlying purpose of this ''timely renewal'' provision in the APA is to protect a licensee who is engaged in an ongoing licensed activity and who has complied with agency rules in applying for a renewed or new license from facing license expiration as the result of delays in the administrative process.

On December 13, 1991, the NRC published the final license renewal rule, 10 CFR, Part 54, with associated changes to 10 CFR, Parts 2, 50, and 140, in the **Federal Register** (56 FR 64943). The statement of considerations (SOC) discussed the basis for establishing the latest date for filing license renewal applications and the timely renewal doctrine (56 FR 64962). The SOC stated that:

> Because the review of a renewal application will involve a review of many complex technical issues, the NRC estimates that the technical review would take approximately 2 years. Any necessary hearing could likely add an additional year or more. Therefore, in the proposed rule, the Commission modified § 2.109 to require that nuclear power plant operating license renewal applications be submitted at least 3 years prior to their expiration in order to take advantage of the timely renewal doctrine.
>
> No specific comment was received concerning the proposal to add a 3-year provision for the timely renewal provision for license renewal. The current regulations require licensees to submit decommissioning plans and related financial assurance information on or about 5 years prior to the expiration of their operating licenses. The Commission has concluded that, for consistency, the deadline for submittal of a license renewal application should be 5 years prior to the expiration of the current operating license. The timely renewal provisions of § 2.109 now reflect the decision that a 5-year time limit is more appropriate.

Thus, the NRC originally estimated that 3 years was needed to review a renewal application and complete any hearing that might be held on the application. The NRC changed its original estimate from 3 years to 5 years to have consistent deadlines for when licensees must submit their decommissioning plans and when they must submit their license renewal application to receive timely renewal protection. The NRC's current schedule for review of license renewal applications is to complete its review and make a decision on issuing the renewed license within 22 months of receipt without a hearing. If a hearing is held, the NRC's model schedule anticipates completion of the NRC's review, the hearing process, and issuance of a decision on issuing the license within 30 months of receipt.

However, it is recognized that the estimate of 30 months for completion of a contested hearing is subject to variation in any given proceeding. A period of 3 years (36 months), nevertheless, is expected to provide sufficient time for performance of a full and adequate safety and environmental review, and completion of the hearing process. Meeting this schedule is based on a complete and sufficient application being submitted and on the review being completed in accordance with the NRC's established license renewal review schedule.

Based on the above, the NRC finds that the special circumstance of 10 CFR 50.12(a)(2)(ii) is present in the particular circumstances of CPS.

It should be noted, among the key matters central to resolution of issues associated with renewal of the operating license and also to the application of the ''timely renewal'' doctrine is the submission of a sufficient application. Completing the license renewal review process on schedule is, of course, dependent on licensee cooperation in meeting established schedules for submittal of any additional information required by the NRC, and the resolution of all issues demonstrating that issuance of a renewed license is warranted.

E. Environmental Considerations

The NRC's approval of the exemption to scheduling requirements belongs to a category of actions that the NRC, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically, the exemption is categorically excluded from further analysis under 10 CFR 51.22(c)(25).

Under 10 CFR 51.22(c)(25), the granting of an exemption from the requirements of any regulation of chapter 10 is a categorical exclusion

provided that (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve certain categories of requirements, including scheduling requirements.

The Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, has determined that the granting of the exemption request involves no significant hazards consideration because allowing the submittal of the license renewal application at least 3 years before the expiration of the existing license while maintaining the protection of the timely renewal provision in 10 CFR 2.109(b) does not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The exemption constitutes a change to the schedule by which Exelon must submit its license renewal application and still receive timely renewal protection and, therefore, is unrelated to any operational restriction. Accordingly, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, and no significant increase in individual or cumulative public or occupational radiation exposure. The exempted regulation is not associated with construction, so there is no significant construction impact. The exempted regulation does not concern the source term (*i.e.,* potential amount of radiation in an accident) nor mitigation. Thus, there is no significant increase in the potential for, or consequences of, a radiological accident.

Therefore, pursuant to 10 CFR 51.22(b) and (c)(25), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

Accordingly, the NRC has determined that, pursuant to 10 CFR 54.15 and 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the NRC hereby grants Exelon Generation Company, LLC, a one-time exemption for CPS, from 10 CFR 54.17(a) to allow the submittal of the CPS license renewal application at least 3 years remaining prior to expiration of the operating license while maintaining the protection of the timely renewal provision in 10 CFR 2.109(b).

Dated at Rockville, Maryland, this 11th day of July 2019.

For the Nuclear Regulatory Commission.

/RA/

Gregory F. Suber,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–15271 Filed 7–17–19; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service; Consolidated Listing of Schedules A, B, and C Exceptions

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This provides the consolidated notice of all agency specific excepted authorities, approved by the Office of Personnel Management (OPM), under Schedule A, B, and C, as of June 30, 2018, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

FOR FURTHER INFORMATION CONTACT: Julia Alford, Senior Executive Resources Services, Senior Executive Service and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: Civil Service Rule VI (5 CFR 6.1) requires the Office of Personnel Management (OPM) to publish notice of exceptions granted under Schedule A, B, and C. Under 5 CFR 213.103(a) it is required that all Schedule A, B, and C appointing authorities available for use by all agencies to be published as regulations in the **Federal Register** (FR) and the Code of Federal Regulations (CFR). Excepted appointing authorities established solely for use by one specific agency do not meet the standard of general applicability prescribed by the **Federal Register** Act for regulations published in either the FR or the CFR. Therefore, 5 CFR 213.103(b) requires monthly publication, in the Notices section of the **Federal Register**, of any Schedule A, B, and C appointing authorities applicable to a single agency. Under 5 CFR 213.103(c) it is required that a consolidated listing of all Schedule A, B, and C authorities, current as of June 30 of each year, be published annually in the Notices section of the **Federal Register** at *www.federalregister.gov/agencies/personnel-management-office.* That notice follows. Governmentwide authorities codified in the CFR are not printed in this notice.

When making appointments under an agency-specific authority, agencies should first list the appropriate Schedule A, B, or C, followed by the applicable number, for example: Schedule A, 213.3104(x)(x). Agencies are reminded that all excepted authorities are subject to the provisions of 5 CFR part 302 unless specifically exempted by OPM at the time of approval.

OPM maintains continuing information on the status of all Schedule A, B, and C appointing authorities. Interested parties needing information about specific authorities during the year may obtain information by writing to the Senior Executive Resource Services, Office of Personnel Management, 1900 E Street NW, Room 7412, Washington, DC 20415, or by calling (202) 606–2246.

The following exceptions are current as of June 30, 2018.

Schedule A

03. Executive Office of the President (Sch. A, 213.3103)

(a) Office of Administration—

(1) Not to exceed 75 positions to provide administrative services and support to the White House Office.

(b) Office of Management and Budget—

(1) Not to exceed 20 positions at grades GS–5/15.

(2) Not to Exceed 34 positions that require unique technical skills needed for the re-designing and re-building of digital interfaces between citizens, businesses, and government as a part of Smarter Information Technology Delivery Initiative. This authority may be used to make permanent, time-limited and temporary appointments to Digital Services Expert positions (GS–301) directly related to the implementation of the Smarter Information Technology Delivery Initiative at the GS–14 to 15 level. No new appointments may be made under this authority after September 30, 2017.

(c) Council on Environmental Quality—

(1) Professional and technical positions in grades GS–9 through 15 on the staff of the Council.

(d)–(f) (Reserved)

(g) National Security Council—

(1) All positions on the staff of the Council.

(h) Office of Science and Technology Policy—

(1) Thirty positions of Senior Policy Analyst, GS–15; Policy Analyst, GS–11/14; and Policy Research Assistant, GS–9, for employment of anyone not to exceed 5 years on projects of a high priority nature.

(i) Office of National Drug Control Policy—

(1) Not to exceed 18 positions, GS–15 and below, of senior policy analysts and other personnel with expertise in drug-related issues and/or technical knowledge to aid in anti-drug abuse efforts.

04. Department of State (Sch. A, 213.3104)

(a) Office of the Secretary—

(1) All positions, GS–15 and below, on the staff of the Family Liaison Office, Director General of the Foreign Service and the Director of Personnel, Office of the Under Secretary for Management.

(2) (Reserved)

(b)–(f) (Reserved)

(g) Bureau of Population, Refugees, and Migration—

(1) Not to exceed 10 positions at grades GS–5 through 11 on the staff of the Bureau.

(h) Bureau of Administration—

(1) (Reserved)

(2) One position of the Director, Art in Embassies Program, GM–1001–15.

(3) (Reserved)

05. Department of the Treasury (Sch. A, 213.3105)

(a) Office of the Secretary—

(1) Not to exceed 20 positions at the equivalent of GS–13 through GS–15 or Senior Level (SL) to supplement permanent staff in the study of complex problems relating to international financial, economic, trade, and energy policies and programs of the Government, when filled by individuals with special qualifications for the particular study being undertaken. Employment under this authority may not exceed 4 years.

(2) Covering no more than 100 positions supplementing permanent staff studying domestic economic and financial policy, with employment not to exceed 4 years.

(3) Not to exceed 100 positions in the Office of the Under Secretary for Terrorism and Financial Intelligence.

(4) Up to 35 temporary or time-limited positions at the GS–9 through 15 grade levels to support the organization, design, and stand-up activities for the Consumer Financial Protection Bureau (CFPB), as mandated by Public Law 111–203. This authority may be used for the following series: GS–201, GS–501, GS–560, GS–1035, GS–1102, GS–1150, GS–1720, GS–1801, and GS–2210. No new appointments may be made under this authority after July 21, 2011, the designated transfer date of the CFPB.

(b)–(d) (Reserved)

(e) Internal Revenue Service—

(1) Twenty positions of investigator for special assignments.

(f) (Reserved)

(g) (Reserved, moved to DOJ)

(h) Office of Financial Stability—

(1) Positions needed to perform investment, risk, financial, compliance, and asset management requiring unique qualifications currently not established by OPM. Positions will be in the Office of Financial Stability and the General Schedule (GS) grade levels 12–15 or Senior Level (SL), for initial employment not to exceed 4 years. No new appointments may be made under this authority after December 31, 2012.

06. Department of Defense (Sch. A, 213.3106)

(a) Office of the Secretary—

(1)–(5) (Reserved)

(6) One Executive Secretary, US–USSR Standing Consultative Commission and Staff Analyst (SALT), Office of the Assistant Secretary of Defense (International Security Affairs).

(b) Entire Department (including the Office of the Secretary of Defense and the Departments of the Army, Navy, and Air Force)—

(1) Dependent School Systems overseas—Professional positions in Military Dependent School systems overseas.

(2) Positions in Attaché 1 systems overseas, including all professional and scientific positions in the Naval Research Branch Office in London.

(3) Positions of clerk-translator, translator, and interpreter overseas.

(4) Positions of Educational Specialist the incumbents of which will serve as Director of Religious Education on the staffs of the chaplains in the military services.

(5) Positions under the program for utilization of alien scientists, approved under pertinent directives administered by the Director of Defense Research and Engineering of the Department of Defense, when occupied by alien scientists initially employed under the program including those who have acquired United States citizenship during such employment.

(6) Positions in overseas installations of the DOD when filled by dependents of military or civilian employees of the U.S. Government residing in the area. Employment under this authority may not extend longer than 2 months following the transfer from the area or separation of a dependent's sponsor: Provided that

(i) A school employee may be permitted to complete the school year; and

(ii) An employee other than a school employee may be permitted to serve up to 1 additional year when the military department concerned finds that the additional employment is in the interest of management.

(7) Twenty secretarial and staff support positions at GS–12 or below on the White House Support Group.

(8) Positions in DOD research and development activities occupied by participants in the DOD Science and Engineering Apprenticeship Program for High School Students. Persons employed under this authority shall be bona fide high school students, at least 14 years old, pursuing courses related to the position occupied and limited to 1,040 working hours a year. Children of DOD employees may be appointed to these positions, notwithstanding the sons and daughters restriction, if the positions are in field activities at remote locations. Appointments under this authority may be made only to positions for which qualification standards established under 5 CFR part 302 are consistent with the education and experience standards established for comparable positions in the competitive service. Appointments under this authority may not be used to extend the service limits contained in any other appointing authority.

(9) (Reserved)

(10) Temporary or time-limited positions in direct support of U.S. Government efforts to rebuild and create an independent, free and secure Iraq and Afghanistan, when no other appropriate appointing authority applies. Positions will generally be located in Iraq or Afghanistan, but may be in other locations, including the United States, when directly supporting operations in Iraq or in Afghanistan. No new appointments may be made under this authority after September 30, 2014.

(11) Not to exceed 3,000 positions that require unique cyber security skills and knowledge to perform cyber risk and strategic analysis, incident handling and malware/vulnerability analysis, program management, distributed control systems security, cyber incident response, cyber exercise facilitation and management, cyber vulnerability detection and assessment, network and systems engineering, enterprise

architecture, investigation, investigative analysis and cyber-related infrastructure inter-dependency analysis. This authority may be used to make permanent, time-limited and temporary appointments in the following occupational series: Security (GS–0080), computer engineers (GS–0854), electronic engineers (GS–0855), computer scientists (GS–1550), operations research (GS–1515), criminal investigators (GS–1811), telecommunications (GS–0391), and IT specialists (GS–2210). Within the scope of this authority, the U.S. Cyber Command is also authorized to hire miscellaneous administrative and program (GS–0301) series when those positions require unique cyber security skills and knowledge. All positions will be at the General Schedule (GS) grade levels 09–15 or equivalent. No new appointments may be made under this authority after December 31, 2017.

(c) (Reserved)

(d) General—

(1) Positions concerned with advising, administering, supervising, or performing work in the collection, processing, analysis, production, evaluation, interpretation, dissemination, and estimation of intelligence information, including scientific and technical positions in the intelligence function; and positions involved in the planning, programming, and management of intelligence resources when, in the opinion of OPM, it is impracticable to examine. This authority does not apply to positions assigned to cryptologic and communications intelligence activities/functions.

(2) Positions involved in intelligence-related work of the cryptologic intelligence activities of the military departments. This includes all positions of intelligence research specialist, and similar positions in the intelligence classification series; all scientific and technical positions involving the applications of engineering, physical, or technical sciences to intelligence work; and professional as well as intelligence technician positions in which a majority of the incumbent's time is spent in advising, administering, supervising, or performing work in the collection, processing, analysis, production, evaluation, interpretation, dissemination, and estimation of intelligence information or in the planning, programming, and management of intelligence resources.

(e) Uniformed Services University of the Health Sciences—

(1) Positions of President, Vice Presidents, Assistant Vice Presidents, Deans, Deputy Deans, Associate Deans, Assistant Deans, Assistants to the President, Assistants to the Vice Presidents, Assistants to the Deans, Professors, Associate Professors, Assistant Professors, Instructors, Visiting Scientists, Research Associates, Senior Research Associates, and Postdoctoral Fellows.

(2) Positions established to perform work on projects funded from grants.

(f) National Defense University—

(1) Not to exceed 16 positions of senior policy analyst, GS–15, at the Strategic Concepts Development Center. Initial appointments to these positions may not exceed 6 years, but may be extended thereafter in 1-, 2-, or 3-year increments, indefinitely.

(g) Defense Communications Agency—

(1) Not to exceed 10 positions at grades GS–10/15 to staff and support the Crisis Management Center at the White House.

(h) Defense Acquisition University—

(1) The Provost and professors.

(i) George C. Marshall European Center for Security Studies, Garmisch, Germany—

(1) The Director, Deputy Director, and positions of professor, instructor, and lecturer at the George C. Marshall European Center for Security Studies, Garmisch, Germany, for initial employment not to exceed 3 years, which may be renewed in increments from 1 to 2 years thereafter.

(j) Asia-Pacific Center for Security Studies, Honolulu, Hawaii—

(1) The Director, Deputy Director, Dean of Academics, Director of College, deputy department chairs, and senior positions of professor, associate professor, and research fellow within the Asia Pacific Center. Appointments may be made not to exceed 3 years and may be extended for periods not to exceed 3 years.

(k) Business Transformation Agency—

(1) Fifty temporary or time-limited (not to exceed four years) positions, at grades GS–11 through GS–15. The authority will be used to appoint persons in the following series: Management and Program Analysis, GS–343: Logistics Management, GS–346; Financial Management Programs, GS–501; Accounting, GS–510; Computer Engineering, GS–854; Business and Industry, GS–1101; Operations Research, GS–1515; Computer Science, GS–1550; General Supply, GS–2001; Supply Program Management, GS–2003; Inventory Management, GS–2010; and Information Technology, GS–2210.

(l) Special Inspector General for Afghanistan—

(1) Positions needed to establish the Special Inspector General for Afghanistan Reconstruction. These positions provide for the independent and objective conduct and supervision of audits and investigations relating to the programs and operations funded with amounts appropriated and otherwise made available for the reconstruction of Afghanistan. These positions are established at General Schedule (GS) grade levels for initial employment not to exceed 3 years and may, with prior approval of OPM, be extended for an additional period of 2 years. No new appointments may be made under this authority after January 31, 2011.

07. Department of the Army (Sch. A, 213.3107)

(a)–(c) (Reserved)

(d) U.S. Military Academy, West Point, New York—

(1) Civilian professors, instructors, teachers (except teachers at the Children's School), Cadet Social Activities Coordinator, Chapel Organist and Choir-Master, Director of Intercollegiate Athletics, Associate Director of Intercollegiate Athletics, Coaches, Facility Manager, Building Manager, three Physical Therapists (Athletic Trainers), Associate Director of Admissions for Plans and Programs, Deputy Director of Alumni Affairs; and Librarian when filled by an officer of the Regular Army retired from active service, and the Military Secretary to the Superintendent when filled by a U.S. Military Academy graduate retired as a regular commissioned officer for disability.

(e)–(f) (Reserved)

(g) Defense Language Institute—

(1) All positions (professors, instructors, lecturers) which require proficiency in a foreign language or knowledge of foreign language teaching methods.

(h) Army War College, Carlisle Barracks, PA—

(1) Positions of professor, instructor, or lecturer associated with courses of instruction of at least 10 months duration for employment not to exceed 5 years, which may be renewed in 1-, 2-, 3-, 4-, or 5-year increments indefinitely thereafter.

(i) (Reserved)

(j) U.S. Military Academy Preparatory School, West Point, New York—

(1) Positions of Academic Director, Department Head, and Instructor.

(k) U.S. Army Command and General Staff College, Fort Leavenworth, Kansas—

(1) Positions of professor, associate professor, assistant professor, and

instructor associated with courses of instruction of at least 10 months duration, for employment not to exceed up to 5 years, which may be renewed in 1-, 2-, 3-, 4-, or 5-year increments indefinitely thereafter.

08. Department of the Navy (Sch. A, 213.3108)

(a) General—

(1)–(14) (Reserved)

(15) Marine positions assigned to a coastal or seagoing vessel operated by a naval activity for research or training purposes.

(16) All positions necessary for the administration and maintenance of the official residence of the Vice President.

(b) Naval Academy, Naval Postgraduate School, and Naval War College—

(1) Professors, Instructors, and Teachers; the Director of Academic Planning, Naval Postgraduate School; and the Librarian, Organist-Choirmaster, Registrar, the Dean of Admissions, and Social Counselors at the Naval Academy.

(c) Chief of Naval Operations—

(1) One position at grade GS–12 or above that will provide technical, managerial, or administrative support on highly classified functions to the Deputy Chief of Naval Operations (Plans, Policy, and Operations).

(d) Military Sealift Command

(1) All positions on vessels operated by the Military Sealift Command.

(e)–(f) (Reserved)

(g) Office of Naval Research—

(1) Scientific and technical positions, GS–13/15, in the Office of Naval Research International Field Office which covers satellite offices within the Far East, Africa, Europe, Latin America, and the South Pacific. Positions are to be filled by personnel having specialized experience in scientific and/or technical disciplines of current interest to the Department of the Navy.

09. Department of the Air Force (Sch. A, 213.3109)

(a) Office of the Secretary—

(1) One Special Assistant in the Office of the Secretary of the Air Force. This position has advisory rather than operating duties except as operating or administrative responsibilities may be exercised in connection with the pilot studies.

(b) General—

(1) Professional, technical, managerial and administrative positions supporting space activities, when approved by the Secretary of the Air Force.

(2) Two hundred positions, serviced by Hill Air Force Base, Utah, engaged in interdepartmental activities in support of national defense projects involving scientific and technical evaluations.

(c) Norton and McClellan Air Force Bases, California—

(1) Not to exceed 20 professional positions, GS–11 through GS–15, in Detachments 6 and 51, SM–ALC, Norton and McClellan Air Force Bases, California, which will provide logistic support management to specialized research and development projects.

(d) U.S. Air Force Academy, Colorado—

(1) (Reserved)

(2) Positions of Professor, Associate Professor, Assistant Professor, and Instructor, in the Dean of Faculty, Commandant of Cadets, Director of Athletics, and Preparatory School of the United States Air Force Academy.

(e) (Reserved)

(f) Air Force Office of Special Investigations—

(1) Positions of Criminal Investigators/Intelligence Research Specialists, GS–5 through GS–15, in the Air Force Office of Special Investigations.

(g) Wright-Patterson Air Force Base, Ohio—

(1) Not to exceed eight positions, GS–12 through 15, in Headquarters Air Force Logistics Command, DCS Material Management, Office of Special Activities, Wright-Patterson Air Force Base, Ohio, which will provide logistic support management staff guidance to classified research and development projects.

(h) Air University, Maxwell Air Force Base, Alabama—

(1) Positions of Professor, Instructor, or Lecturer.

(i) Air Force Institute of Technology, Wright-Patterson Air Force Base, Ohio—

(1) Civilian deans and professors.

(j) Air Force Logistics Command—

(1) One Supervisory Logistics Management Specialist, GM–346–14, in Detachment 2, 2762 Logistics Management Squadron (Special), Greenville, Texas.

(k) Wright-Patterson AFB, Ohio—

(1) One position of Supervisory Logistics Management Specialist, GS–346–15, in the 2762nd Logistics Squadron (Special), at Wright-Patterson Air Force Base, Ohio.

(l) Air National Guard Readiness Center—

(1) One position of Commander, Air National Guard Readiness Center, Andrews Air Force Base, Maryland.

10. Department of Justice (Sch. A, 213.3110)

(a) General—

(1) Deputy U.S. Marshals employed on an hourly basis for intermittent service.

(2) Positions at GS–15 and below on the staff of an office of a special counsel.

(3)–(5) (Reserved)

(6) Positions of Program Manager and Assistant Program Manager supporting the International Criminal Investigative Training Assistance Program in foreign countries. Initial appointments under this authority may not exceed 2 years, but may be extended in 1-year increments for the duration of the in-country program.

(7) Positions necessary throughout DOJ, for the excepted service transfer of NDIC employees hired under Schedule A, 213.3110(d). Authority expires September 30, 2012.

(b) (Reserved)

(c) Drug Enforcement Administration—

(1) (Reserved)

(2) Four hundred positions of Intelligence Research Agent and/or Intelligence Operation Specialist in the GS–132 series, grades GS–9 through GS–15.

(3) Not to exceed 200 positions of Criminal Investigator (Special Agent). New appointments may be made under this authority only at grades GS–7/11.

(d) (Reserved, moved to Justice)

(e) Bureau of Alcohol, Tobacco, and Firearms—

(1) One hundred positions of Criminal Investigator for special assignments.

(2) One non-permanent Senior Level (SL) Criminal Investigator to serve as a senior advisor to the Assistant Director (Firearms, Explosives, and Arson).

11. Department of Homeland Security (Sch. A, 213.3111)

(a) (Revoked 11/19/2009)

(b) Law Enforcement Policy—

(1) Ten positions for oversight policy and direction of sensitive law enforcement activities.

(c) Homeland Security Labor Relations Board/Homeland Security Mandatory Removal Board—

(1) Up to 15 Senior Level and General Schedule (or equivalent) positions.

(d) General—

(1) Not to exceed 1,000 positions to perform cyber risk and strategic analysis, incident handling and malware/vulnerability analysis, program management, distributed control systems security, cyber incident response, cyber exercise facilitation and management, cyber vulnerability detection and assessment, network and systems engineering, enterprise architecture, intelligence analysis, investigation, investigative analysis and cyber-related infrastructure

interdependency analysis requiring unique qualifications currently not established by OPM. Positions will be at the General Schedule (GS) grade levels 09–15. No new appointments may be made under this authority after the completion of regulations implementing the Border Patrol Agency Pay Reform Act of 2014 or January 15, 2019.

(e) Papago Indian Agency—Not to exceed 25 positions of Immigration and Customs Enforcement (ICE) Tactical Officers (Shadow Wolves) in the Papago Indian Agency in the State of Arizona when filled by the appointment of persons of one-fourth or more Indian blood. (Formerly 213.3105(b)(9))

(f) U.S. Citizenship and Immigration Services

(1) Reserved. (Formerly 213.3110(b)(1))

(2) Not to exceed 500 positions of interpreters and language specialists, GS–1040–5/9. (Formerly 213.3110(b)(2))

(3) Reserved. (Formerly 213.3110(b)(3))

(g) U.S. Immigration and Customs Enforcement—

(1) Not to exceed 200 staff positions, GS–15 and below for an emergency staff to provide health related services to foreign entrants. (Formerly 213.3116(b)(16))

(h) Federal Emergency Management Agency—

(1) Field positions at grades GS–15 and below, or equivalent, which are engaged in work directly related to unique response efforts to environmental emergencies not covered by the Disaster Relief Act of 1974, Public Law 93–288, as amended. Employment under this authority may not exceed 36 months on any single emergency. Persons may not be employed under this authority for long-term duties or for work not directly necessitated by the emergency response effort. (Formerly 213.3195(a))

(2) Not to exceed 30 positions at grades GS–15 and below in the Offices of Executive Administration, General Counsel, Inspector General, Comptroller, Public Affairs, Personnel, Acquisition Management, and the State and Local Program and Support Directorate which are engaged in work directly related to unique response efforts to environmental emergencies not covered by the Disaster Relief Act of 1974, Public Law 93–288, as amended. Employment under this authority may not exceed 36 months on any single emergency, or for long-term duties or work not directly necessitated by the emergency response effort. No one may be reappointed under this authority for service in connection with a different emergency unless at least 6 months have elapsed since the individual's latest appointment under this authority. (Formerly 213.3195(b))

(3) Not to exceed 350 professional and technical positions at grades GS–5 through GS–15, or equivalent, in Mobile Emergency Response Support Detachments (MERS). (Formerly 213.3195(c))

(i) U.S. Coast Guard—

(1) Reserved. (Formerly 213.3194(a))

(2) Lamplighters. (Formerly 213.3194(b))

(3) Professors, Associate Professors, Assistant Professors, Instructors, one Principal Librarian, one Cadet Hostess, and one Psychologist (Counseling) at the Coast Guard Academy, New London, Connecticut. (Formerly 213.3194(c))

12. Department of the Interior (Sch. A, 213.3112)

(a) General—

(1) Technical, maintenance, and clerical positions at or below grades GS–7, WG–10, or equivalent, in the field service of the Department of the Interior, when filled by the appointment of persons who are certified as maintaining a permanent and exclusive residence within, or contiguous to, a field activity or district, and as being dependent for livelihood primarily upon employment available within the field activity of the Department.

(2) All positions on Government-owned ships or vessels operated by the Department of the Interior.

(3) Temporary or seasonal caretakers at temporarily closed camps or improved areas to maintain grounds, buildings, or other structures and prevent damages or theft of Government property. Such appointments shall not extend beyond 130 working days a year without the prior approval of OPM.

(4) Temporary, intermittent, or seasonal field assistants at GS–7, or its equivalent, and below in such areas as forestry, range management, soils, engineering, fishery and wildlife management, and with surveying parties. Employment under this authority may not exceed 180 working days a year.

(5) Temporary positions established in the field service of the Department for emergency forest and range fire prevention or suppression and blister rust control for not to exceed 180 working days a year: Provided, that an employee may work as many as 220 working days a year when employment beyond 180 days is required to cope with extended fire seasons or sudden emergencies such as fire, flood, storm, or other unforeseen situations involving potential loss of life or property.

(6) Persons employed in field positions, the work of which is financed jointly by the Department of the Interior and cooperating persons or organizations outside the Federal service.

(7) All positions in the Bureau of Indian Affairs and other positions in the Department of the Interior directly and primarily related to providing services to Indians when filled by the appointment of Indians. The Secretary of the Interior is responsible for defining the term ''Indian.''

(8) Temporary, intermittent, or seasonal positions at GS–7 or below in Alaska, as follows: Positions in nonprofessional mining activities, such as those of drillers, miners, caterpillar operators, and samplers. Employment under this authority shall not exceed 180 working days a year and shall be appropriate only when the activity is carried on in a remote or isolated area and there is a shortage of available candidates for the positions.

(9) Temporary, part-time, or intermittent employment of mechanics, skilled laborers, equipment operators, and tradesmen on construction, repair, or maintenance work not to exceed 180 working days a year in Alaska, when the activity is carried on in a remote or isolated area and there is a shortage of available candidates for the positions.

(10) Seasonal airplane pilots and airplane mechanics in Alaska, not to exceed 180 working days a year.

(11) Temporary staff positions in the Youth Conservation Corps Centers operated by the Department of the Interior. Employment under this authority shall not exceed 11 weeks a year except with prior approval of OPM.

(12) Positions in the Youth Conservation Corps for which pay is fixed at the Federal minimum wage rate. Employment under this authority may not exceed 10 weeks.

(b) (Reserved)

(c) Indian Arts and Crafts Board—

(1) The Executive Director

(d) (Reserved)

(e) Office of the Assistant Secretary, Territorial and International Affairs—

(1) (Reserved)

(2) Not to exceed four positions of Territorial Management Interns, grades GS–5, GS–7, or GS–9, when filled by territorial residents who are U.S. citizens from the Virgin Islands or Guam; U.S. nationals from American Samoa; or in the case of the Northern Marianas, will become U.S. citizens upon termination of the U.S. trusteeship. Employment under this authority may not exceed 6 months.

(3) (Reserved)

(4) Special Assistants to the Governor of American Samoa who perform specialized administrative, professional, technical, and scientific duties as members of his or her immediate staff.

(f) National Park Service—

(1) (Reserved)

(2) Positions established for the administration of Kalaupapa National Historic Park, Molokai, Hawaii, when filled by appointment of qualified patients and Native Hawaiians, as provided by Public Law 95–565.

(3) Seven full-time permanent and 31 temporary, part-time, or intermittent positions in the Redwood National Park, California, which are needed for rehabilitation of the park, as provided by Public Law 95–250.

(4) One Special Representative of the Director.

(5) All positions in the Grand Portage National Monument, Minnesota, when filled by the appointment of recognized members of the Minnesota Chippewa Tribe.

(g) Bureau of Reclamation—

(1) Appraisers and examiners employed on a temporary, intermittent, or part-time basis on special valuation or prospective-entrymen-review projects where knowledge of local values on conditions or other specialized qualifications not possessed by regular Bureau employees are required for successful results. Employment under this provision shall not exceed 130 working days a year in any individual case: Provided, that such employment may, with prior approval of OPM, be extended for not to exceed an additional 50 working days in any single year.

(h) Office of the Deputy Assistant Secretary for Territorial Affairs—

(1) Positions of Territorial Management Interns, GS–5, when filled by persons selected by the Government of the Trust Territory of the Pacific Islands. No appointment may extend beyond 1 year.

13. Department of Agriculture (Sch. A, 213.3113)

(a) General—

(1) Agents employed in field positions the work of which is financed jointly by the Department and cooperating persons, organizations, or governmental agencies outside the Federal service. Except for positions for which selection is jointly made by the Department and the cooperating organization, this authority is not applicable to positions in the Agricultural Research Service or the National Agricultural Statistics Service. This authority is not applicable to the following positions in the Agricultural Marketing Service: Agricultural commodity grader (grain) and (meat), (poultry), and (dairy), agricultural commodity aid (grain), and tobacco inspection positions.

(2)–(4) (Reserved)

(5) Temporary, intermittent, or seasonal employment in the field service of the Department in positions at and below GS–7 and WG–10 in the following types of positions: Field assistants for sub professional services; agricultural helpers, helper-leaders, and workers in the Agricultural Research Service and the Animal and Plant Health Inspection Service; and subject to prior OPM approval granted in the calendar year in which the appointment is to be made, other clerical, trades, crafts, and manual labor positions. Total employment under this subparagraph may not exceed 180 working days in a service year: Provided, that an employee may work as many as 220 working days in a service year when employment beyond 180 days is required to cope with extended fire seasons or sudden emergencies such as fire, flood, storm, or other unforeseen situations involving potential loss of life or property. This paragraph does not cover trades, crafts, and manual labor positions covered by paragraph (i) of Sec. 213.3102 or positions within the Forest Service.

(6)–(7) (Reserved)

(b)–(c) (Reserved)

(d) Farm Service Agency—

(1) (Reserved)

(2) Members of State Committees: Provided, that employment under this authority shall be limited to temporary intermittent (WAE) positions whose principal duties involve administering farm programs within the State consistent with legislative and Departmental requirements and reviewing national procedures and policies for adaptation at State and local levels within established parameters. Individual appointments under this authority are for 1 year and may be extended only by the Secretary of Agriculture or his designee. Members of State Committees serve at the pleasure of the Secretary.

(e) Rural Development—

(1) (Reserved)

(2) County committeemen to consider, recommend, and advise with respect to the Rural Development program.

(3)–(5) (Reserved)

(6) Professional and clerical positions in the Trust Territory of the Pacific Islands when occupied by indigenous residents of the Territory to provide financial assistance pursuant to current authorizing statutes.

(f) Agricultural Marketing Service—

(1) Positions of Agricultural Commodity Graders, Agricultural Commodity Technicians, and Agricultural Commodity Aids at grades GS–9 and below in the tobacco, dairy, and poultry commodities; Meat Acceptance Specialists, GS–11 and below; Clerks, Office Automation Clerks, and Computer Clerks at GS–5 and below; Clerk-Typists at grades GS–4 and below; and Laborers under the Wage System. Employment under this authority is limited to either 1,280 hours or 180 days in a service year.

(2) Positions of Agricultural Commodity Graders, Agricultural Commodity Technicians, and Agricultural Commodity Aids at grades GS–11 and below in the cotton, raisin, peanut, and processed and fresh fruit and vegetable commodities and the following positions in support of these commodities: Clerks, Office Automation Clerks, and Computer Clerks and Operators at GS–5 and below; Clerk-Typists at grades GS–4 and below; and, under the Federal Wage System, High Volume Instrumentation (HVI) Operators and HVI Operator Leaders at WG/WL–2 and below, respectively, Instrument Mechanics/Workers/Helpers at WG–10 and below, and Laborers. Employment under this authority may not exceed 180 days in a service year. In unforeseen situations such as bad weather or crop conditions, unanticipated plant demands, or increased imports, employees may work up to 240 days in a service year. Cotton Agricultural Commodity Graders, GS–5, may be employed as trainees for the first appointment for an initial period of 6 months for training without regard to the service year limitation.

(3) Milk Market Administrators

(4) All positions on the staffs of the Milk Market Administrators.

(g)–(k) (Reserved)

(l) Food Safety and Inspection Service—

(1)–(2) (Reserved)

(3) Positions of Meat and Poultry Inspectors (Veterinarians at GS–11 and below and non-Veterinarians at appropriate grades below GS–11) for employment on a temporary, intermittent, or seasonal basis, not to exceed 1,280 hours a year.

(m) Grain Inspection, Packers and Stockyards Administration—

(1) One hundred and fifty positions of Agricultural Commodity Aid (Grain), GS–2/4; 100 positions of Agricultural Commodity Technician (Grain), GS–4/7; and 60 positions of Agricultural Commodity Grader (Grain), GS–5/9, for temporary employment on a part-time, intermittent, or seasonal basis not to exceed 1,280 hours in a service year.

(n) Alternative Agricultural Research and Commercialization Corporation—

(1) Executive Director

14. Department of Commerce (Sch. A, 213.3114)

(a) General—

(1)–(2) (Reserved)

(3) Not to exceed 50 scientific and technical positions whose duties are performed primarily in the Antarctic. Incumbents of these positions may be stationed in the continental United States for periods of orientation, training, analysis of data, and report writing.

(b)–(c) (Reserved)

(d) Bureau of the Census—

(1) Positions in support of decennial operations (including decennial pre-tests). Appointments may be made on a time limited basis that lasts the duration of decennial operations but may not exceed 7 years. Extensions beyond 7 years may be requested on a case-by-case basis.

(2) Positions of clerk, field representative, field leader, and field supervisor in support of data collection operations (non-decennial operations). Appointments may be made on a permanent or a time-limited basis. Appointments made on a time limited basis may not exceed 4 years. Extensions beyond 4 years may be requested on a case-by-case basis.

(e)–(h) (Reserved)

(i) Office of the Under Secretary for International Trade—

(1) Fifteen positions at GS–12 and above in specialized fields relating to international trade or commerce in units under the jurisdiction of the Under Secretary for International Trade. Incumbents will be assigned to advisory rather than to operating duties, except as operating and administrative responsibility may be required for the conduct of pilot studies or special projects. Employment under this authority will not exceed 2 years for an individual appointee.

(2) (Reserved)

(3) Not to exceed 15 positions in grades GS–12 through GS–15, to be filled by persons qualified as industrial or marketing specialists; who possess specialized knowledge and experience in industrial production, industrial operations and related problems, market structure and trends, retail and wholesale trade practices, distribution channels and costs, or business financing and credit procedures applicable to one or more of the current segments of U.S. industry served by the Under Secretary for International Trade, and the subordinate components of his organization which are involved in Domestic Business matters. Appointments under this authority may be made for a period not to exceed 2 years and may, with prior OPM approval, be extended for an additional 2 years.

(j) National Oceanic and Atmospheric Administration—

(1)–(2) (Reserved)

(3) All civilian positions on vessels operated by the National Ocean Service.

(4) Temporary positions required in connection with the surveying operations of the field service of the National Ocean Service. Appointment to such positions shall not exceed 8 months in any 1 calendar year.

(k) (Reserved)

(l) National Telecommunication and Information Administration—

(1) Thirty-eight professional positions in grades GS–13 through GS–15.

15. Department of Labor (Sch. A, 213.3115)

(a) Office of the Secretary—

(1) Chairman and five members, Employees' Compensation Appeals Board.

(2) Chairman and eight members, Benefits Review Board.

(b)–(c) (Reserved)

(d) Employment and Training Administration—

(1) Not to exceed 10 positions of Supervisory Manpower Development Specialist and Manpower Development Specialist, GS–7/15, in the Division of Indian and Native American Programs, when filled by the appointment of persons of one-fourth or more Indian blood. These positions require direct contact with Indian tribes and communities for the development and administration of comprehensive employment and training programs.

16. Department of Health and Human Services (Sch. A, 213.3116)

(a) General—

(1) Intermittent positions, at GS–15 and below and WG–10 and below, on teams under the National Disaster Medical System including Disaster Medical Assistance Teams and specialty teams, to respond to disasters, emergencies, and incidents/events involving medical, mortuary and public health needs.

(b) Public Health Service—

(1) (Reserved)

(2) Positions at Government sanatoria when filled by patients during treatment or convalescence.

(3) (Reserved)

(4) Positions concerned with problems in preventive medicine financed or participated in by the Department of Health and Human Services and a cooperating State, county, municipality, incorporated organization, or an individual in which at least one-half of the expense is contributed by the participating agency either in salaries, quarters, materials, equipment, or other necessary elements in the carrying on of the work.

(5)–(6) (Reserved)

(7) Not to exceed 50 positions associated with health screening programs for refugees.

(8) All positions in the Public Health Service and other positions in the Department of Health and Human Services directly and primarily related to providing services to Indians when filled by the appointment of Indians. The Secretary of Health and Human Services is responsible for defining the term ''Indian.''

(9) (Reserved)

(10) Health care positions of the National Health Service Corps for employment of any one individual not to exceed 4 years of service in health manpower shortage areas.

(11)–(15) (Reserved)

(c)–(e) (Reserved)

(f) The President's Council on Physical Fitness—

(1) Four staff assistants.

17. Department of Education (Sch. A, 213.3117)

(a) Positions concerned with problems in education financed and participated in by the Department of Education and a cooperating State educational agency, or university or college, in which there is joint responsibility for selection and supervision of employees, and at least one-half of the expense is contributed by the cooperating agency in salaries, quarters, materials, equipment, or other necessary elements in the carrying on of the work.

18. Environmental Protection Agency (sch. A, 213.3118)

24. Board of Governors, Federal Reserve System (Sch. A, 213.3124)

(a) All positions

27. Department of Veterans Affairs (Sch. A, 213.3127)

(a) Construction Division—

(1) Temporary construction workers paid from ''purchase and hire'' funds and appointed for not to exceed the duration of a construction project.

(b) Alcoholism Treatment Units and Drug Dependence Treatment Centers—

(1) Not to exceed 400 positions of rehabilitation counselors, GS–3 through GS–11, in Alcoholism Treatment Units and Drug Dependence Treatment Centers, when filled by former patients.

(c) Board of Veterans' Appeals—

(1) Positions, GS–15, when filled by a member of the Board. Except as

provided by section 201(d) of Public Law 100–687, appointments under this authority shall be for a term of 9 years, and may be renewed.

(2) Positions, GS–15, when filled by a non-member of the Board who is awaiting Presidential approval for appointment as a Board member.

(d) Vietnam Era Veterans Readjustment Counseling Service—

(1) Not to exceed 600 positions at grades GS–3 through GS–11, involved in the Department's Vietnam Era Veterans Readjustment Counseling Service.

(e) Not to Exceed 75 positions that require unique technical skills needed for the re-designing and re-building of digital interfaces between citizens, businesses, and government as a part of Smarter Information Technology Delivery Initiative. This authority may be used to make permanent, time-limited and temporary appointments to non-supervisory Digital Services Expert positions (GS–301) directly related to the implementation of the Smarter Information Technology Delivery Initiative at the GS–15 level. No new appointments may be made under this authority after September 30, 2017.

32. Small Business Administration (Sch. A, 213.3132)

(a) When the President under 42 U.S.C. 1855–1855g, the Secretary of Agriculture under 7 U.S.C. 1961, or the Small Business Administration under 15 U.S.C. 636(b)(1) declares an area to be a disaster area, positions filled by time-limited appointment of employees to make and administer disaster loans in the area under the Small Business Act, as amended. Service under this authority may not exceed 4 years, and no more than 2 years may be spent on a single disaster. Exception to this time limit may only be made with prior Office of Personnel Management approval. Appointments under this authority may not be used to extend the 2-year service limit contained below. No one may be appointed under this authority to positions engaged in long-term maintenance of loan portfolios.

(b) When the President under 42 U.S.C. 1855–1855g, the Secretary of Agriculture under 7 U.S.C. 1961, or the Small Business Administration under 15 U.S.C. 636(b)(1) declares an area to be a disaster area, positions filled by time-limited appointment of employees to make and administer disaster loans in that area under the Small Business Act, as amended. No one may serve under this authority for more than an aggregate of 2 years without a break in service of at least 6 months. Persons who have had more than 2 years of service under paragraph (a) of this section must have a break in service of at least 8 months following such service before appointment under this authority. No one may be appointed under this authority to positions engaged in long-term maintenance of loan portfolios.

33. Federal Deposit Insurance Corporation (Sch. A, 213.3133)

(a)–(b) (Reserved)

(c) Temporary or time-limited positions that are directly related with resolving failing insured depository institutions; financial companies; or brokers and dealers; covered by the Dodd-Frank Wall Street Reform and Consumer Protection Act, including but not limited to, the marketing and sale of institutions and any associated assets; paying insured depositors; and managing receivership estates and all associated receivership management activities, up to termination. Time limited appointments under this authority may not exceed 7 years.

36. U.S. Soldiers' and Airmen's Home (Sch. A, 213.3136)

(a) (Reserved)

(b) Positions when filled by member-residents of the Home.

37. General Services Administration (Sch. A, 213.3137)

(a) Not to Exceed 203 positions that require unique technical skills needed for the re-designing and re-building of digital interfaces between citizens, businesses, and government as a part of Smarter Information Technology Delivery Initiative. This authority may be used nationwide to make permanent, time-limited and temporary appointments to Digital Services Expert positions (GS–301) directly related to the implementation of the Smarter Information Technology Delivery Initiative at the GS–11 to 15 level. No new appointments may be made under this authority after September 30, 2017.

46. Selective Service System (Sch. A, 213.3146)

(a) State Directors

48. National Aeronautics and Space Administration (Sch. A, 213.3148)

(a) One hundred and fifty alien scientists having special qualifications in the fields of aeronautical and space research where such employment is deemed by the Administrator of the National Aeronautics and Space Administration to be necessary in the public interest.

55. Social Security Administration (Sch. A, 213.3155)

(a) Arizona District Offices—

(1) Six positions of Social Insurance Representative in the district offices of the Social Security Administration in the State of Arizona when filled by the appointment of persons of one-fourth or more Indian blood.

(b) New Mexico—

(1) Seven positions of Social Insurance Representative in the district offices of the Social Security Administration in the State of New Mexico when filled by the appointment of persons of one-fourth or more Indian blood.

(c) Alaska—

(1) Two positions of Social Insurance Representative in the district offices of the Social Security Administration in the State of Alaska when filled by the appointments of persons of one-fourth or more Alaskan Native blood (Eskimos, Indians, or Aleuts).

62. The President's Crime Prevention Council (Sch. A, 213.3162)

(a) (Reserved)

65. Chemical Safety and Hazard Investigation Board (Sch. A, 213.3165)

(a) (Reserved)

(b) (Reserved)

66. Court Services and Offender Supervision Agency of the District of Columbia (Sch. A, 213.3166)

(a) (Reserved, expired 3/31/2004)

70. Millennium Challenge Corporation (MCC) (Sch. A, 213.3170)

(a) (Reserved, expired 9/30/2007)

(b)

(1) Positions of Resident Country Director and Deputy Resident Country Director, Threshold Director and Deputy Threshold Director. The length of appointments will correspond to the length or term of the compact agreements made between the MCC and the country in which the MCC will work, plus one additional year to cover pre- and post-compact agreement related activities.

74. Smithsonian Institution (Sch. A, 213.3174)

(a) (Reserved)

(b) Smithsonian Tropical Research Institute—All positions located in Panama which are part of or which support the Smithsonian Tropical Research Institute.

(c) National Museum of the American Indian—Positions at GS–15 and below requiring knowledge of, and experience in, tribal customs and culture. Such positions comprise approximately 10 percent of the Museum's positions and, generally, do not include secretarial, clerical, administrative, or program support positions.

75. Woodrow Wilson International Center for Scholars (Sch. A, 213.3175)

(a) One Asian Studies Program Administrator, one International Security Studies Program Administrator, one Latin American Program Administrator, one Russian Studies Program Administrator, two Social Science Program Administrators, one Middle East Studies Program Administrator, one African Studies Program Administrator, one Global Sustainability and Resilience Program Administrator, one Canadian Studies Program Administrator; one China Studies Program Administrator, and one Science, Technology and Innovation Program Administrator.

78. Community Development Financial Institutions Fund (Sch. A, 213.3178)

(a) (Reserved, expired 9/23/1998)

80. Utah Reclamation and Conservation Commission (Sch. A, 213.3180)

(a) Executive Director

82. National Foundation on the Arts and the Humanities (Sch. A, 213.3182)

(a) National Endowment for the Arts—

(1) Artistic and related positions at grades GS–13 through GS–15 engaged in the review, evaluation and administration of applications and grants supporting the arts, related research and assessment, policy and program development, arts education, access programs and advocacy, or evaluation of critical arts projects and outreach programs. Duties require artistic stature, in-depth knowledge of arts disciplines and/or artistic-related leadership qualities.

90. African Development Foundation (Sch. A, 213.3190)

(a) One Enterprise Development Fund Manager. Appointment is limited to four years unless extended by OPM.

91. Office of Personnel Management (Sch. A, 213.3191)

(a)–(c) (Reserved)

(d) Part-time and intermittent positions of test examiners at grades GS–8 and below.

94. Department of Transportation (Sch. A, 213.3194)

(a)–(d) (Reserved)

(e) Maritime Administration—

(1)–(2) (Reserved)

(3) All positions on Government-owned vessels or those bareboats chartered to the Government and operated by or for the Maritime Administration.

(4)–(5) (Reserved)

(6) U.S. Merchant Marine Academy, positions of: Professors, Instructors, and Teachers, including heads of Departments of Physical Education and Athletics, Humanities, Mathematics and Science, Maritime Law and Economics, Nautical Science, and Engineering; Coordinator of Shipboard Training; the Commandant of Midshipmen, the Assistant Commandant of Midshipmen; Director of Music; three Battalion Officers; three Regimental Affairs Officers; and one Training Administrator.

(7) U.S. Merchant Marine Academy positions of: Associate Dean; Registrar; Director of Admissions; Assistant Director of Admissions; Director, Office of External Affairs; Placement Officer; Administrative Librarian; Shipboard Training Assistant; three Academy Training Representatives; and one Education Program Assistant.

(f) Up to 40 positions at the GS–13 through 15 grade levels and within authorized SL allocations necessary to support the following credit agency programs of the Department: The Federal Highway Administration's Transportation Infrastructure Finance and Innovation Act Program, the Federal Railroad Administration's Railroad Rehabilitation and Improvement Financing Program, the Federal Maritime Administration's Title XI Program, and the Office of the Secretary's Office of Budget and Programs Credit Staff. This authority may be used to make temporary, time-limited, or permanent appointments, as the DOT deems appropriate, in the following occupational series: Director or Deputy Director SL–301/340, Origination Team Lead SL–301, Deputy Director/Senior Financial Analyst GS–1160, Origination Financial Policy Advisor GS–301, Credit Budgeting Team Lead GS–1160, Credit Budgeting Financial Analysts GS–1160, Portfolio Monitoring Lead SL–1160, Portfolio Monitoring Financial Analyst GS–1160, Financial Analyst GS–1160. No new appointments may be made under this authority after December 31, 2014.

95. (Reserved)

Schedule B

03. Executive Office of the President (Sch. B, 213.3203)

(a) (Reserved)

(b) Office of the Special Representative for Trade Negotiations—

(1) Seventeen positions of economist at grades GS–12 through GS–15.

04. Department of State (Sch. B, 213.3204)

(a)(1) One non-permanent senior level position to serve as Science and Technology Advisor to the Secretary.

(b)–(c) (Reserved)

(d) Seventeen positions on the household staff of the President's Guest House (Blair and Blair-Lee Houses).

(e) (Reserved)

(f) Scientific, professional, and technical positions at grades GS–12 to GS–15 when filled by persons having special qualifications in foreign policy matters. Total employment under this authority may not exceed 4 years.

05. Department of the Treasury (Sch. B, 213.3205)

(a) Positions of Deputy Comptroller of the Currency, Chief National Bank Examiner, Assistant Chief National Bank Examiner, Regional Administrator of National Banks, Deputy Regional Administrator of National Banks, Assistant to the Comptroller of the Currency, National Bank Examiner, Associate National Bank Examiner, and Assistant National Bank Examiner, whose salaries are paid from assessments against national banks and other financial institutions.

(b)–(c) (Reserved)

(d) (Reserved) Transferred to 213.3211(b)

(e) (Reserved) Transferred to 213.3210(f)

06. Department of Defense (Sch. B, 213.3206)

(a) Office of the Secretary—

(1) (Reserved)

(2) Professional positions at GS–11 through GS–15 involving systems, costs, and economic analysis functions in the Office of the Assistant Secretary (Program Analysis and Evaluation); and in the Office of the Deputy Assistant Secretary (Systems Policy and Information) in the Office of the Assistant Secretary (Comptroller).

(3)–(4) (Reserved)

(5) Four Net Assessment Analysts.

(b) Interdepartmental activities—

(1) Seven positions to provide general administration, general art and information, photography, and/or visual information support to the White House Photographic Service.

(2) Eight positions, GS–15 or below, in the White House Military Office, providing support for airlift operations, special events, security, and/or administrative services to the Office of the President.

(c) National Defense University—

(1) Sixty-one positions of Professor, GS–13/15, for employment of any one

individual on an initial appointment not to exceed 3 years, which may be renewed in any increment from 1 to 6 years indefinitely thereafter.

(d) General—

(1) One position of Law Enforcement Liaison Officer (Drugs), GS–301–15, U.S. European Command.

(2) Acquisition positions at grades GS–5 through GS–11, whose incumbents have successfully completed the required course of education as participants in the Department of Defense scholarship program authorized under 10 U.S.C. 1744.

(e) Office of the Inspector General—

(1) Positions of Criminal Investigator, GS–1811–5/15.

(f) Department of Defense Polygraph Institute, Fort McClellan, Alabama—

(1) One Director, GM–15.

(g) Defense Security Assistance Agency—All faculty members with instructor and research duties at the Defense Institute of Security Assistance Management, Wright Patterson Air Force Base, Dayton, Ohio. Individual appointments under this authority will be for an initial 3-year period, which may be followed by an appointment of indefinite duration.

07. Department of the Army (Sch. B, 213.3207)

(a) U.S. Army Command and General Staff College—

(1) Seven positions of professors, instructors, and education specialists. Total employment of any individual under this authority may not exceed 4 years.

08. Department of the Navy (Sch. B, 213.3208)

(a) Naval Underwater Systems Center, New London, Connecticut—

(1) One position of Oceanographer, grade GS–14, to function as project director and manager for research in the weapons systems applications of ocean eddies.

(b) Armed Forces Staff College, Norfolk, Virginia—All civilian faculty positions of professors, instructors, and teachers on the staff of the Armed Forces Staff College, Norfolk, Virginia.

(c) Defense Personnel Security Research and Education Center—One Director and four Research Psychologists at the professor or GS–15 level.

(d) Marine Corps Command and Staff College—All civilian professor positions.

(e) Executive Dining facilities at the Pentagon—One position of Staff Assistant, GS–301, whose incumbent will manage the Navy's Executive Dining facilities at the Pentagon.

(f) (Reserved)

09. Department of the Air Force (Sch. B, 213.3209)

(a) Air Research Institute at the Air University, Maxwell Air Force Base, Alabama—Not to exceed four interdisciplinary positions for the Air Research Institute at the Air University, Maxwell Air Force Base, Alabama, for employment to complete studies proposed by candidates and acceptable to the Air Force. Initial appointments are made not to exceed 3 years, with an option to renew or extend the appointments in increments of 1-, 2-, or 3-years indefinitely thereafter.

(b)–(c) (Reserved)

(d) Air University—Positions of Instructor or professional academic staff at the Air University associated with courses of instruction of varying durations, for employment not to exceed 3 years, which may be renewed for an indefinite period thereafter.

(e) U.S. Air Force Academy, Colorado—One position of Director of Development and Alumni Programs, GS–301–13.

10. Department of Justice (Sch. B, 213.3210)

(a) Drug Enforcement Administration—Criminal Investigator (Special Agent) positions in the Drug Enforcement Administration. New appointments may be made under this authority only at grades GS–5 through 11. Service under the authority may not exceed 4 years. Appointments made under this authority may be converted to career or career-conditional appointments under the provisions of Executive Order 12230, subject to conditions agreed upon between the Department and OPM.

(b) (Reserved)

(c) Not to exceed 400 positions at grades GS–5 through 15 assigned to regional task forces established to conduct special investigations to combat drug trafficking and organized crime.

(d) (Reserved)

(e) United States Trustees—Positions, other than secretarial, GS–6 through GS–15, requiring knowledge of the bankruptcy process, on the staff of the offices of United States Trustees or the Executive Office for U.S. Trustees.

(f) Bureau of Alcohol, Tobacco, and Firearms

(1) Positions, grades GS–5 through GS–12 (or equivalent), of Criminal Investigator. Service under this authority may not exceed 3 years and 120 days.

11. Department of Homeland Security (Sch. B, 213.3211)

(a) Coast Guard.

(1) (Reserved)

(b) Secret Service—Positions concerned with the protection of the life and safety of the President and members of his immediate family, or other persons for whom similar protective services are prescribed by law, when filled in accordance with special appointment procedures approved by OPM. Service under this authority may not exceed:

(1) A total of 4 years; or

(2) 120 days following completion of the service required for conversion under Executive Order 11203.

13. Department of Agriculture (Sch. B, 213.3213)

(a) Foreign Agricultural Service—

(1) Positions of a project nature involved in international technical assistance activities. Service under this authority may not exceed 5 years on a single project for any individual unless delayed completion of a project justifies an extension up to but not exceeding 2 years.

(b) General—

(1) Temporary positions of professional Research Scientists, GS–15 or below, in the Agricultural Research Service, Economic Research Service, and the Forest Service, when such positions are established to support the Research Associateship Program and are filled by persons having a doctoral degree in an appropriate field of study for research activities of mutual interest to appointees and the agency. Appointments are limited to proposals approved by the appropriate Administrator. Appointments may be made for initial periods not to exceed 2 years and may be extended for up to 2 additional years. Extensions beyond 4 years, up to a maximum of 2 additional years, may be granted, but only in very rare and unusual circumstances, as determined by the Human Resources Officer for the Research, Education, and Economics Mission Area, or the Human Resources Officer, Forest Service.

(2) Not to exceed 55 Executive Director positions, GM–301–14/15, with the State Rural Development Councils in support of the Presidential Rural Development Initiative.

14. Department of Commerce (Sch. B, 213.3214)

(a) Bureau of the Census—

(1) (Reserved)

(2) Not to exceed 50 Community Services Specialist positions at the equivalent of GS–5 through 12.

(b)–(c) (Reserved)

(d) National Telecommunications and Information Administration—

(1) Not to exceed 10 Telecommunications Policy Analysts,

grades GS–11 through 15. Employment under this authority may not exceed 2 years.

15. Department of Labor (Sch. B, 213.3215)

(a) *Administrative Review Board*—Chair and a maximum of four additional Members.

(b) (Reserved)

(c) Bureau of International Labor Affairs—

(1) Positions in the Office of Foreign Relations, which are paid by outside funding sources under contracts for specific international labor market technical assistance projects. Appointments under this authority may not be extended beyond the expiration date of the project.

17. Department of Education (Sch. B, 213.3217)

(a) Seventy-five positions, not to exceed GS–13, of a professional or analytical nature when filled by persons, other than college faculty members or candidates working toward college degrees, who are participating in mid-career development programs authorized by Federal statute or regulation, or sponsored by private nonprofit organizations, when a period of work experience is a requirement for completion of an organized study program. Employment under this authority shall not exceed 1 year.

(b) Fifty positions, GS–7 through GS–11, concerned with advising on education policies, practices, and procedures under unusual and abnormal conditions. Persons employed under this provision must be bona fide elementary school and high school teachers. Appointments under this authority may be made for a period of not to exceed 1 year, and may, with the prior approval of the Office of Personnel Management, be extended for an additional period of 1 year.

27. Department of Veterans Affairs (Sch. B, 213.3227)

(a) Not to exceed 800 principal investigatory, scientific, professional, and technical positions at grades GS–11 and above in the medical research program.

(b) Not to exceed 25 Criminal Investigator (Undercover) positions, GS–1811, in grades 5 through 12, conducting undercover investigations in the Veterans Health Administration (VA) supervised by the VA, Office of Inspector General. Initial appointments shall be greater than 1 year, but not to exceed 4 years and may be extended indefinitely in 1-year increments.

28. Broadcasting Board of Governors (Sch. B, 213.3228)

(a) International Broadcasting Bureau—

(1) Not to exceed 200 positions at grades GS–15 and below in the Office of Cuba Broadcasting. Appointments may not be made under this authority to administrative, clerical, and technical support positions.

36. U.S. Soldiers' and Airmen's Home (Sch. B, 213.3236)

(a) (Reserved)

(b) Director, Health Care Services; Director, Member Services; Director, Logistics; and Director, Plans and Programs.

40. National Archives and Records Administration (Sch. B, 213.3240)

(a) Executive Director, National Historical Publications and Records Commission.

48. National Aeronautics and Space Administration (Sch. B, 213.3248)

(a) Not to exceed 40 positions of Astronaut Candidates at grades GS–11 through 15. Employment under this authority may not exceed 3 years.

50. Consumer Financial Protection Bureau (Sch. B, 213.3250)

(a) One position of Deputy Director; and one position of Associate Director of the Division of Supervision, Enforcement, and Fair Lending.

55. Social Security Administration (Sch. B, 213.3255)

(a) (Reserved)

74. Smithsonian Institution (Sch. B, 213.3274)

(a) (Reserved)

(b) Freer Gallery of Art—

(1) Not to exceed four Oriental Art Restoration Specialists at grades GS–9 through GS–15.

76. Appalachian Regional Commission (Sch. B, 213.3276)

(a) Two Program Coordinators.

78. Armed Forces Retirement Home (Sch. B, 213.3278)

(a) Naval Home, Gulfport, Mississippi—

(1) One Resource Management Officer position and one Public Works Officer position, GS/GM–15 and below.

82. National Foundation on the Arts and the Humanities (Sch. B, 213.3282)

(a) (Reserved)

(b) National Endowment for the Humanities—

(1) Professional positions at grades GS–11 through GS–15 engaged in the review, evaluation, and administration of grants supporting scholarship, education, and public programs in the humanities, the duties of which require in-depth knowledge of a discipline of the humanities.

91. Office of Personnel Management (Sch. B, 213.3291)

(a) Not to exceed eight positions of Associate Director at the Executive Seminar Centers at grades GS–13 and GS–14. Appointments may be made for any period up to 3 years and may be extended without prior approval for any individual. Not more than half of the authorized faculty positions at any one Executive Seminar Center may be filled under this authority.

(b) Center for Leadership Development—No more than 72 positions of faculty members at grades GS–13 through GS–15. Initial appointments under this authority may be made for any period up to 3 years and may be extended in 1, 2, or 3 year increments.

SCHEDULE C

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF AGRICULTURE	Office of Animal and Plant Health Inspection Service.	Confidential Assistant	DA180131	06/01/2018
	Farm Service Agency	State Director—New Jersey	DA180077	11/09/2017
		State Executive Director (11)	DA180104	01/26/2018
			DA180114	01/26/2018
			DA180011	10/20/2017
			DA180014	10/20/2017
			DA180026	10/20/2017
			DA170200	10/23/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
			DA180038	10/23/2017
			DA180024	11/03/2017
			DA180066	11/06/2017
			DA180009	11/08/2017
			DA180073	11/13/2017
		State Executive Director—Alabama	DA180049	11/27/2017
		State Executive Director—Alaska ..	DA180039	10/23/2017
		State Executive Director—Arizona	DA180109	01/16/2018
		State Executive Director—Arkansas.	DA180006	10/20/2017
		State Executive Director—California.	DA180062	11/06/2017
		State Executive Director—Delaware.	DA180140	03/23/2018
		State Executive Director—Georgia	DA180031	10/23/2017
		State Executive Director—Hawaii ..	DA180084	11/13/2017
		State Executive Director—Illinois (2).	DA180035	10/20/2017
			DA180092	11/13/2017
		State Executive Director—Indiana	DA180010	10/20/2017
		State Executive Director—Iowa	DA180046	10/20/2017
		State Executive Director—Kansas	DA170197	11/03/2017
		State Executive Director—Kentucky.	DA180007	10/20/2017
		State Executive Director—Louisiana.	DA170201	10/30/2017
		State Executive Director—Maine ...	DA180015	10/20/2017
		State Executive Director—Michigan	DA180028	10/20/2017
		State Executive Director—Mississippi.	DA180013	10/20/2017
		State Executive Director—Nebraska.	DA180068	11/06/2017
		State Executive Director—Nevada	DA180043	10/20/2017
		State Executive Director—New York.	DA180058	11/03/2017
		State Executive Director—North Dakota.	DA180067	11/06/2017
		State Executive Director—Ohio	DA180004	11/09/2017
		State Executive Director—Oklahoma.	DA180022	10/20/2017
		State Executive Director—Oregon	DA180059	11/03/2017
		State Executive Director—Pennsylvania.	DA180086	11/09/2017
		State Executive Director—Rhode Island.	DA180170	04/20/2018
		State Executive Director—South Dakota.	DA180075	11/13/2017
		State Executive Director—Tennessee.	DA180061	11/03/2017
		State Executive Director—Utah	DA180065	11/06/2017
		State Executive Director—Vermont	DA180085	11/09/2017
		State Executive Director—Virginia	DA180023	10/20/2017
		State Executive Director—Washington.	DA170190	09/13/2017
		State Executive Director—West Virginia.	DA180107	01/26/2018
		State Executive Director—Wisconsin.	DA170205	10/20/2017
		State Executive Director—Wyoming (2).	DA180036	10/23/2017
			DA180091	11/13/2017
		State Executive Director, Idaho	DA180044	11/03/2017
		State Executive Director, North Carolina.	DA180070	11/29/2017
	Office of Food and Nutrition Service.	Confidential Assistant	DA170196	10/06/2017
	Office of Forest Service	Senior Advisor	DA180127	03/08/2018
	Office of Communications	Advance Lead	DA180152	03/29/2018
		Deputy Press Secretary	DA180113	02/14/2018
		Press Assistant (2)	DA180165	04/27/2018
			DA170175	08/09/2017
		Press Secretary	DA170169	07/21/2017
		Speechwriter	DA170174	08/09/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Assistant Secretary for Congressional Relations.	Associate Director	DA180159	04/20/2018
		Confidential Assistant (2)	DA180149	04/13/2018
			DA180019	10/05/2017
		Deputy Director for Intergovernmental Affairs.	DA170172	08/03/2017
		Director, Intergovernmental Affairs	DA180174	05/08/2018
		Policy and Congressional Advisor	DA180175	06/08/2018
		Senior Advisor	DA170186	09/22/2017
		Special Assistant	DA180056	11/03/2017
		Staff Assistant (3)	DA180119	02/22/2018
			DA180118	02/27/2018
			DA180157	04/13/2018
	Office of the Assistant to the Secretary for Rural Development.	Confidential Assistant	DA180129	02/27/2018
		Chief of Staff	DA180100	12/15/2017
	Office of the General Counsel	Senior Counsel	DA180098	12/08/2017
	Office of the Secretary	Confidential Assistant	DA180115	01/23/2018
		Director of Advance	DA180151	03/28/2018
		Director of Policy Coordination	DA180158	05/08/2018
		Director of the Office of Faith Based and Neighborhood Outreach.	DA180101	12/21/2017
		Director, Tribal Relations	DA180096	12/05/2017
		Special Assistant (2)	DA180102	02/06/2018
			DA170176	09/19/2017
		Staff Assistant (2)	DA180143	03/29/2018
			DA170193	09/22/2017
		White House Liaison	DA170173	08/03/2017
	Office of the Under Secretary for Farm Production and Conservation.	Staff Assistant	DA180181	05/16/2018
	Office of the Under Secretary for Food Safety.	Confidential Assistant	DA180148	05/24/2018
	Office of the Under Secretary for Food, Nutrition and Consumer Services.	Confidential Assistant	DA170195	10/30/2017
	Office of the Under Secretary for Marketing and Regulatory Programs.	Confidential Assistant	DA180093	11/29/2017
	Office of Under Secretary for Natural Resources and Environment.	Staff Assistant	DA180169	05/24/2018
	Office of Rural Business Service	Senior Advisor	DA180166	04/27/2018
	Office of Rural Housing Service	Chief of Staff	DA180055	12/05/2017
		Confidential Assistant (2)	DA180128	02/28/2018
			DA180150	03/28/2018
		Senior Advisor (2)	DA180125	02/20/2018
			DA180095	11/27/2017
		State Director (5)	DA180017	10/20/2017
			DA180146	05/16/2018
			DA180020	10/23/2017
			DA180025	10/23/2017
			DA180064	11/06/2017
		State Director—Alabama	DA180057	11/07/2017
		State Director—Alaska	DA170204	10/23/2017
		State Director—Arizona	DA180052	10/27/2017
		State Director—Arkansas	DA180003	10/20/2017
		State Director—California	DA180063	11/06/2017
		State Director—Florida	DA180074	11/09/2017
		State Director—Hawaii	DA180079	11/09/2017
		State Director—Idaho	DA170185	08/30/2017
		State Director—Illinois (2)	DA180034	10/23/2017
			DA180090	11/13/2017
		State Director—Indiana	DA180078	11/09/2017
		State Director—Iowa	DA170202	10/23/2017
		State Director—Kansas	DA180060	11/03/2017
		State Director—Kentucky	DA180002	10/23/2017
		State Director—Louisiana	DA180126	05/30/2018
		State Director—Maine	DA180030	11/01/2017
		State Director—Massachusetts	DA180012	10/20/2017
		State Director—Michigan	DA180001	10/20/2017
		State Director—Minnesota	DA180029	11/01/2017
		State Director—Mississippi	DA180027	10/23/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
		State Director—Missouri	DA180040	10/20/2017
		State Director—Nebraska	DA180050	11/07/2017
		State Director—Nevada	DA180042	10/20/2017
		State Director—New Mexico	DA180018	11/09/2017
		State Director—North Carolina	DA180072	11/09/2017
		State Director—North Dakota	DA180089	11/16/2017
		State Director—Ohio	DA180081	11/09/2017
		State Director—Oklahoma	DA180080	11/09/2017
		State Director—Oregon	DA180008	10/20/2017
		State Director—Pennsylvania	DA180032	10/20/2017
		State Director—Puerto Rico	DA180168	04/16/2018
		State Director—South Carolina	DA180071	11/06/2017
		State Director—South Dakota	DA180083	11/09/2017
		State Director—Tennessee	DA180048	11/03/2017
		State Director—Texas	DA170203	11/09/2017
		State Director—Utah	DA180069	11/06/2017
		State Director—Virginia	DA180088	11/09/2017
		State Director—Washington	DA180037	10/23/2017
		State Director—West Virginia	DA180041	10/23/2017
		State Director—Wisconsin	DA180087	11/09/2017
		State Director—Wyoming	DA180016	10/23/2017
		State Director, New Hampshire	DA180076	11/09/2017
	Office of Rural Utilities Service	Strategic Program Advisor	DA180185	05/08/2018
APPALACHIAN REGIONAL COMMISSION.	Appalachian Regional Commission	Program Analyst	AP180001	05/25/2018
BROADCASTING BOARD OF GOVERNORS.	Broadcasting Board of Governors	Senior Advisor	IB170005	07/11/2017
		Special Advisor for Strategy	IB170006	09/11/2017
DEPARTMENT OF COMMERCE	Office of Advocacy Center	Policy Assistant	DC180009	11/14/2017
	Office of the Assistant Secretary Legislative and Intergovernmental Affairs.	Confidential Assistant	DC170155	08/04/2017
	Bureau of Industry and Security	Director of Congressional and Public Affairs.	DC180149	06/13/2018
		Special Advisor	DC170158	10/23/2017
	Office of Director General of the United States and Foreign Commercial Service and Assistant Secretary for Global Markets.	Senior Director	DC180011	11/03/2017
		Senior Advisor for China	DC180063	12/15/2017
	Immediate Office	Special Advisor	DC180001	10/18/2017
	Office of International Trade Administration.	Special Assistant	DC180142	05/25/2018
	Office of Executive Secretariat	Confidential Assistant	DC180136	06/01/2018
	Associate Director, Office of Executive Secretariat.	DC180108	06/13/2018	
	Office of Legislative and Intergovernmental Affairs.	Associate Director for Oversight	DC180073	01/18/2018
	Director of Intergovernmental Affairs.	DC180141	06/05/2018	
	Office of Policy and Strategic Planning.	Policy Assistant	DC170164	10/05/2017
	Office of Public Affairs	Deputy Press Secretary	DC180147	06/08/2018
	Office of Scheduling and Advance	Advance Assistant	DC180076	02/22/2018
		Senior Scheduler	DC180083	02/22/2018
		Scheduler	DC170146	07/05/2017
		Deputy Director of Protocol	DC170167	10/31/2017
	Office of the Chief of Staff	Confidential Assistant	DC180104	03/19/2018
	Office of the Deputy Assistant Secretary.	Special Advisor	DC180123	05/08/2018
		Senior Advisor and Director of Strategic Initiatives.	DC180148	06/08/2018
	Office of the Director	Chief of Congressional Affairs	DC180090	03/12/2018
		Special Advisor	DC170169	10/04/2017
	Office of the General Counsel	Senior Counsel (2)	DC180130	04/20/2018
			DC180131	04/20/2018
	Office of the Under Secretary	Senior Advisor	DC180100	03/29/2018
		Senior Advisor for International Trade Administration.	DC180003	10/24/2017
		Senior Advisor for Advance	DC180004	10/24/2017
	Office of Under Secretary	Policy Advisor	DC180053	12/20/2017
		Special Advisor (2)	DC180052	11/27/2017
			DC180055	12/20/2017

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Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of White House Liaison	Confidential Assistant (2)	DC180087	02/22/2018
			DC180155	06/21/2018
		Deputy Director, Office of White House Liaison.	DC170168	10/11/2017
	Office of Patent and Trademark Office.	Chief Communications Officer	DC180114	03/20/2018
COMMISSION ON CIVIL RIGHTS	Office of Commission on Civil Rights.	Special Assistant	CC180001	04/20/2018
COMMODITY FUTURES TRADING COMMISSION.	Office of the Chief Economist	Chief Economist	CT170011	07/07/2017
CONSUMER PRODUCT SAFETY COMMISSION.	Office of Commissioners	Special Assistant (Legal) (3)	PS180002	01/10/2018
			PS170005	08/30/2017
			PS170006	08/30/2017
		Executive Assistant	PS180001	10/11/2017
	Office of Communications	Supervisory Public Affairs Specialist.	PS170009	01/10/2018
DEPARTMENT OF DEFENSE	Office of the Assistant Secretary of Defense (Asian and Pacific Security Affairs).	Special Assistant (Afghanistan, Pakistan, and Central Asia).	DD170189	07/05/2017
		Special Assistant (South and Southeast Asia).	DD170219	08/25/2017
		Special Assistant for East Asia	DD170225	09/14/2017
			DD170236	10/11/2017
	Office of the Assistant Secretary of Defense (Homeland Defense and Global Security).	Special Assistant (Cyber)	DD170198	07/31/2017
		Special Assistant for Defense Continuity and Mission Assurance.	DD170216	08/04/2017
	Office of the Assistant Secretary of Defense (International Security Affairs).	Special Assistant for African Affairs	DD180002	10/18/2017
		Special Assistant for Middle East (3).	DD170209	08/04/2017
			DD170212	08/08/2017
			DD180004	11/01/2017
		Special Assistant for Russia, Ukraine and Eurasia.	DD170208	08/04/2017
	Office of the Assistant Secretary of Defense (Legislative Affairs).	Director of Strategic Communications for Legislative Affairs.	DD180067	03/16/2018
		Special Assistant (Legislative Affairs) (5).	DD180074	03/22/2018
			DD180091	06/08/2018
			DD180093	06/08/2018
			DD170175	08/04/2017
			DD170161	10/03/2017
		Special Assistant for Installations, Environment, and Energy.	DD170235	10/06/2017
	Office of the Assistant Secretary of Defense (Manpower and Reserve Affairs).	Confidential Assistant for Manpower and Reserve Affairs.	DD170210	08/04/2017
		Special Assistant for Manpower and Reserve Affairs.	DD170215	08/09/2017
	Office of the Assistant Secretary of Defense (Special Operations/Low Intensity Conflict).	Special Assistant and Combating Terrorism (2).	DD180028	01/18/2018
			DD180029	01/23/2018
		Special Assistant (Stability and Humanitarian Affairs) (2).	DD170191	07/07/2017
			DD170217	08/04/2017
		Special Assistant (Counternarcotic and Global Threats).	DD180003	09/21/2017
		Special Assistant for Special Operations and Combating Terrorism (2).	DD180032	12/20/2017
			DD170229	09/20/2017
	Office of the Assistant to the Secretary of Defense (Public Affairs).	Special Assistant for Public Affairs	DD170233	10/06/2017
	Office of the Chief Management Officer.	Special Assistant (2)	DD180078	04/11/2018
			DD180099	06/13/2018
	Office of the Secretary	Director of Communications	DD180072	03/29/2018
	Office of the Secretary of Defense	Advance Officer (3)	DD170139	08/30/2017
			DD170222	08/31/2017
			DD180027	12/20/2017
		Director of Operations/Confidential Assistant.	DD170205	08/04/2017
		Director, Travel Operations	DD170203	08/04/2017
		Protocol Officer (2)	DD180015	11/09/2017
			DD180018	11/15/2017
		Reader—Special Assistant	DD170099	10/23/2017
		Special Assistant (2)	DD180075	03/27/2018
			DD170168	07/06/2017
		Speechwriter	DD180034	12/21/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Under Secretary of Defense (Acquisition, Technology, and Logistics).	Special Assistant (Manufacturing and Industrial Base Policy).	DD180051	02/14/2018
		Director of Operations for Research and Engineering.	DD180065	03/16/2018
		Special Assistant (Logistics and Materiel Readiness).	DD180086	05/08/2018
		Special Assistant for Acquisition	DD170221	08/30/2017
	Office of the Under Secretary of Defense (Comptroller).	Special Assistant (Comptroller) (3)	DD180042	01/30/2018
			DD180039	01/31/2018
			DD180055	01/31/2018
	Office of the Under Secretary of Defense (Personnel and Readiness).	Director of Communications for Personnel and Readiness.	DD180080	04/06/2018
		Special Assistant	DD180083	04/20/2018
		Special Assistant (Personnel and Readiness).	DD170223	09/12/2017
		Senior Advisor (Personnel and Readiness).	DD180014	10/30/2017
	Office of the Under Secretary of Defense (Policy).	Special Assistant	DD170201	07/21/2017
		Special Assistant for Homeland Defense and Defense Support of Civil Authorities.	DD180066	03/19/2018
		Special Assistant for Policy	DD180026	12/15/2017
		Special Assistant (Afghanistan, Pakistan and Central Asia).	DD180056	02/22/2018
		Special Assistant (East Asia)	DD170202	07/21/2017
		Special Assistant (Europe and North Atlantic Treaty Organization).	DD180024	12/15/2017
		Special Assistant (Russia, Ukraine and Eurasia Policy).	DD180059	02/14/2018
		Special Assistant (Space Policy) ...	DD180041	01/30/2018
		Special Assistant (Special Operations and Counterterrorism).	DD180043	01/31/2018
		Special Assistant, Defeat Islamic State of Iraq and Syria Task Force.	DD180013	11/06/2017
	Washington Headquarters Services	Defense Fellow (8)	DD180008	02/05/2018
			DD180058	02/06/2018
			DD180060	03/16/2018
			DD180076	03/28/2018
			DD170194	07/14/2017
			DD170226	09/14/2017
			DD180009	10/31/2017
			DD180017	11/02/2017
		Staff Assistant	DD170185	07/05/2017
DEPARTMENT OF THE AIR FORCE.	Office of Deputy Under Secretary (International Affairs).	Special Assistant	DF170014	10/30/2017
	Office of Assistant Secretary Air Force for Financial Management and Comptroller.	Financial Specialist	DF170013	09/06/2017
	Office of Assistant Secretary of the Air Force for Manpower and Reserve Affairs.	Special Assistant	DF180003	10/23/2017
	Office of the Secretary	Special Assistant and Speechwriter	DF180016	03/29/2018
		Special Assistant (3)	DF180021	06/01/2018
			DF170010	07/26/2017
			DF180005	11/03/2017
	Office of the Under Secretary	Special Assistant	DF180004	11/09/2017
DEPARTMENT OF THE ARMY	Office Assistant Secretary Army (Civil Works).	Special Assistant (Civil Works) (2)	DW180021	04/06/2018
			DW180032	05/24/2018
		Special Assistant (Strategy and Acquisition Reform).	DW180031	05/16/2018
	Office Assistant Secretary Army (Financial Management and Comptroller).	Special Assistant (Financial Management and Comptroller).	DW170026	08/25/2017
	Office Assistant Secretary Army (Installations, Energy and Environment).	Confidential Assistant (Installations, Energy and Environment).	DW180037	06/21/2018
		Special Assistant (Installations, Energy and Environment).	DW180003	10/26/2017
	Office Assistant Secretary Army (Manpower and Reserve Affairs).	Special Assistant (Manpower and Reserve Affairs) (2).	DW170041	02/27/2018
			DW180033	05/16/2018

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office Deputy Under Secretary of Army.	Personal and Confidential Assistant.	DW170025	07/06/2017
DEPARTMENT OF THE NAVY	Office of the Assistant Secretary of Navy (Energy, Installations and Environment).	Special Assistant	DN170025	08/29/2017
	Office of the Assistant Secretary of Navy (Financial Management and Comptroller).	Special Assistant	DN170020	08/17/2017
	Office of the Assistant Secretary of Navy (Manpower and Reserve Affairs).	Special Assistant (Manpower and Reserve Affairs).	DN170024	08/29/2017
	Office of the Under Secretary of the Navy.	Special Assistant for Financial Management and Comptroller.	DN180014	03/16/2018
		Special Assistant	DN170022	08/17/2017
	Department of the Navy	Special Assistant	DN180003	10/23/2017
DEPARTMENT OF EDUCATION ...	Office for Civil Rights	Attorney Advisor	DB170140	09/05/2017
	Office of Career Technical and Adult Education.	Special Assistant	DB170127	07/21/2017
		Confidential Assistant	DB180017	12/01/2017
	Office of Communications and Outreach.	Confidential Assistant (5)	DB180042	04/27/2018
			DB180046	05/24/2018
			DB170134	08/11/2017
			DB170141	09/11/2017
			DB180004	10/13/2017
		Special Assistant (2)	DB180014	11/13/2017
			DB180013	12/01/2017
	Office of Elementary and Secondary Education.	Confidential Assistant (3)	DB180023	01/18/2018
			DB180026	02/06/2018
			DB180045	06/01/2018
	Office of Legislation and Congressional Affairs.	Confidential Assistant	DB170145	10/13/2017
		Special Assistant (Supervisory)	DB180025	12/21/2017
	Office of Planning, Evaluation and Policy Development.	Confidential Assistant (2)	DB170146	10/11/2017
			DB180020	12/19/2017
	Office of Postsecondary Education	Senior Advisor	DB180033	02/14/2018
		Confidential Assistant	DB170137	09/06/2017
	Office of Special Education and Rehabilitative Services.	Confidential Assistant	DB180024	01/18/2018
	Office of the General Counsel	Attorney Advisor (3)	DB180039	04/27/2018
			DB170132	08/07/2017
			DB170144	10/05/2017
	Office of the Secretary	Confidential Assistant (4)	DB170120	07/07/2017
			DB170135	08/02/2017
			DB180010	11/09/2017
			DB180011	11/09/2017
		Confidential Assistant (Protocol)	DB180041	04/09/2018
		Executive Director, White House Initiative on Asian Americans and Pacific Islanders.	DB180009	11/03/2017
		Special Assistant (4)	DB170136	08/04/2017
			DB170138	08/17/2017
			DB180005	10/26/2017
			DB180003	11/20/2017
	Office of the Under Secretary	Executive Director, White House Initiatives on Educational Excellence for Hispanics.	DB180029	01/31/2018
		Executive Director, White House Initiative on Historically Black Colleges and Universities.	DB180032	02/12/2018
		Confidential Assistant	DB180050	06/21/2018
		Special Assistant (Supervisory) (2)	DB170139	08/25/2017
			DB180008	10/30/2017
DEPARTMENT OF ENERGY	Office of Advanced Research Projects Agency—Energy.	Executive Support Specialist	DE180090	05/17/2018
		Senior Advisor and Chief of Staff ..	DE170187	07/31/2017
	Office of the Assistant Secretary for Congressional and Intergovernmental Affairs.	Special Assistant	DE180007	01/30/2018
		Senior Legislative Advisor	DE180042	01/30/2018
		Senior Advisor	DE180106	06/08/2018
		External Affairs Specialist	DE180102	06/14/2018
		Director of External Affairs	DE170225	10/23/2017
	Office of the Assistant Secretary for Electricity Delivery and Energy Reliability.	Senior Advisor for External Affairs	DE180024	01/26/2018
		Chief of Staff	DE180045	02/13/2018

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Assistant Secretary for Energy Efficiency and Renewable Energy.	Special Assistant	DE180086	06/08/2018
		Senior Advisor	DE170189	09/06/2017
	Office of the Assistant Secretary for Environmental Management.	Senior Advisor	DE180105	05/23/2018
	Office of the Assistant Secretary for Fossil Energy.	Senior Advisor	DE180060	03/23/2018
	Office of the Assistant Secretary for International Affairs.	Senior Advisor	DE180094	06/14/2018
		Senior Advisor for Operations	DE180092	06/21/2018
		Senior Advisor and Chief of Staff	DE170224	10/05/2017
	Office of the Associate Under Secretary for Environment, Health, Safety and Security.	Senior Advisor—Veterans Relations.	DE170218	10/18/2017
		Senior Project Advisor	DE170219	10/23/2017
	Office of National Nuclear Security Administration.	Senior Advisor	DE180066	04/06/2018
	Office of Economic Impact and Diversity.	Special Advisor	DE180033	03/12/2018
	Office of General Counsel	Senior Advisor	DE180046	01/31/2018
	Office of Indian Energy Policy and Programs.	Deputy Director, Office of Indian Energy Policy and Programs.	DE180015	11/29/2017
	Office of Management	Senior Congressional Correspondence Advisor.	DE180068	04/20/2018
		Special Assistant	DE170207	08/30/2017
	Office of Policy	Senior Analyst for Energy Security	DE180002	10/23/2017
	Office of Public Affairs	Digital Director	DE180028	01/30/2018
		Associate Deputy Press Secretary	DE170191	03/01/2018
		Special Assistant	DE180077	05/16/2018
		Principal Deputy Press Secretary	DE180123	06/18/2018
		Deputy Press Secretary	DE170184	07/18/2017
		Writer-Editor (Chief Speechwriter)	DE170203	08/30/2017
		Director of Strategic Communications and Messaging.	DE170221	09/20/2017
	Office of Scheduling and Advance	Scheduler (2)	DE180049	02/02/2018
			DE170185	07/21/2017
		Special Assistant	DE170198	07/26/2017
		Director of Advance	DE170200	08/10/2017
		Advance Lead	DE170215	09/07/2017
	Office of Science	Special Advisor (2)	DE170211	09/22/2017
			DE170210	09/26/2017
		Physical Scientist (Senior Advisor)	DE180016	11/29/2017
	Office of the Chief Financial Officer	Special Assistant	DE180067	04/20/2018
		Senior Advisor	DE180087	06/08/2018
	Office of the Chief Information Officer.	Special Assistant	DE170201	09/07/2017
	Office of the Deputy Secretary	Special Advisor (2)	DE170179	07/21/2017
			DE170196	08/08/2017
	Office of the Secretary	Senior Support Specialist	DE180043	01/23/2018
		Special Advisor	DE180034	02/20/2018
		Special Assistant (3)	DE180071	04/27/2018
			DE180118	06/21/2018
			DE170227	10/06/2017
		White House Liaison	DE170160	09/12/2017
	Office of the Secretary of Energy Advisory Board.	Deputy Director, Office of Secretarial Boards and Councils.	DE180029	01/23/2018
		Director, Office of Secretarial Boards and Councils.	DE180006	11/02/2017
	Office of the Under Secretary	Senior Advisor	DE180023	01/26/2018
		Scheduler	DE180032	01/31/2018
		Chief of Staff	DE180012	11/09/2017
		Special Assistant	DE180014	11/20/2017
	Under Secretary for Science	Senior Advisor	DE180048	02/22/2018
ENVIRONMENTAL PROTECTION AGENCY.	Office of Public Affairs	Press Secretary (2)	EP180004	11/09/2017
			EP180006	11/20/2017
	Office of Public Engagement and Environmental Education.	Associate Administrator for the Office of Public Engagement and Environmental Education.	EP170082	08/09/2017
	Office of the Administrator	Deputy Director for Scheduling and Advance.	EP180002	10/20/2017
		Director of Scheduling and Advance.	EP170074	07/05/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
		Senior Advisor for Agriculture Policy.	EP180001	10/23/2017
		Senior Advisor for Water and Cross-Cutting Initiatives.	EP170073	07/05/2017
		Special Assistant (2)	EP170076	07/13/2017
			EP180003	10/17/2017
		Special Assistant for Scheduling and Advance.	EP170075	07/13/2017
	Office of the Assistant Administrator for Land and Emergency Management.	Senior Counsel for Land and Emergency Management.	EP180021	12/20/2017
	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Special Advisor	EP180026	03/01/2018
		Special Advisor for Office of Congressional and Intergovernmental Relations.	EP180059	06/13/2018
		Special Assistant	EP170078	07/13/2017
		Special Assistant for Congressional Relations.	EP170063	07/06/2017
		Special Assistant for the Office of Congressional and Intergovernmental Relations.	EP180067	06/21/2018
	Office of the Chief Financial Officer	Special Advisor for Budgets and Audits.	EP180013	11/09/2017
	Office of the General Counsel	Senior Counsel	EP170097	09/12/2017
		Deputy General Counsel	EP170095	09/14/2017
	Region X—Seattle, Washington	Senior Advisor for Public Engagement.	EP180008	11/29/2017
	Region II—New York, New York	Special Assistant	EP180015	11/29/2017
	Region VII—Lenexa, Kansas	Deputy Regional Administrator	EP170093	09/22/2017
	Region VIII—Denver, Colorado	Attorney-Adviser (General)	EP180070	06/13/2018
	Region IX—San Francisco, California.	Senior Advisor	EP180061	05/10/2018
EXPORT-IMPORT BANK	Office of Communications	Senior Vice President for Communications.	EB180003	12/08/2017
	Office of the Chairman	Financial Advisor	EB170015	07/21/2017
		Senior Advisor	EB170019	07/21/2017
		Advisor	EB170005	07/25/2017
		Senior Advisor for Governmental Affairs.	EB180002	11/20/2017
	Office of the General Counsel	Senior Vice President and General Counsel.	EB180004	01/31/2018
FEDERAL DEPOSIT INSURANCE CORPORATION.	Federal Deposit Insurance Corporation.	Deputy for External Affairs	FD180002	06/22/2018
FEDERAL ENERGY REGULATORY COMMISSION.	Office of the Chairman	Confidential Assistant	DR170007	08/28/2017
FEDERAL TRADE COMMISSION	Office of the Chairman	Director, Office of Policy Planning	FT180001	03/29/2018
		Director, Office of Public Affairs	FT180002	03/29/2018
		Economist	FT180004	05/02/2018
		Technology Advisor	FT180008	06/04/2018
GENERAL SERVICES ADMINISTRATION.	Office of Federal Acquisition Service.	Confidential Assistant	GS180008	01/16/2018
		Executive Director	GS170045	09/01/2017
	Great Lakes Region	Senior Advisor	GS170036	08/04/2017
	Northwest/Arctic Region	Senior Advisor for Technology and to the Regional Administrator.	GS180026	04/06/2018
	Office of Administrative Services	Director, Office of Accountability and Transparency.	GS180033	05/24/2018
	Office of Congressional and Intergovernmental Affairs.	Communications Advisor	GS170044	07/31/2017
		Deputy Associate Administrator for Congressional and Intergovernmental Affairs.	GS180005	11/20/2017
	Office of General Counsel	Counsel	GS180025	04/16/2018
	Office of Governmentwide Policy	Senior Advisor for Governmentwide Policy.	GS170050	09/06/2017
	Office of Strategic Communications	Press Secretary and Deputy Associate Administrator for Media Affairs.	GS180031	05/09/2018
	Office of the Administrator	Confidential Assistant	GS180023	03/13/2018
		Special Assistant	GS170048	08/30/2017
		White House Liaison	GS180003	11/13/2017
	Office of Regional Administrators	Senior Advisor	GS180015	01/29/2018
		Special Assistant	GS180006	12/21/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Heartland Region	Senior Advisor (2)	GS180001	01/16/2018
			GS180004	11/22/2017
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of the Administration for Children and Families.	Policy Advisor (3)	DH180059	03/06/2018
			DH180053	04/04/2018
			DH170306	08/04/2017
		Advisor (2)	DH180134	05/09/2018
			DH180145	05/24/2018
		Confidential Assistant	DH180164	06/13/2018
	Office of the Administration for Community Living.	Policy Advisor	DH180063	04/06/2018
	Office of the Center for Consumer Information and Insurance Oversight.	Policy Advisor	DH180082	03/08/2018
		Senior Advisor	DH170342	10/30/2017
	Office of the Centers for Disease Control and Prevention.	Deputy Chief of Staff	DH180114	04/27/2018
	Office of the Centers for Medicare and Medicaid Services.	Senior Advisor for Medicare	DH180064	03/06/2018
		Special Assistant	DH180088	03/23/2018
		Director of Strategic Communications.	DH180106	04/06/2018
		Advisor for Medicare	DH180178	06/08/2018
		Policy Advisor	DH170320	08/22/2017
		Senior Advisor	DH170309	09/06/2017
		Director of Strategic Communications.	DH180025	12/20/2017
	Office of Food and Drug Administration.	Senior Advisor (2)	DH180144	05/24/2018
			DH180004	11/07/2017
	Office of Health Resources and Services Administration Office of the Administrator.	Policy Advisor	DH170346	10/13/2017
	Office of Indian Health Service	Senior Advisor	DH180054	03/06/2018
		Senior Advisor, Indian Health Service.	DH170299	07/20/2017
	Office for Civil Rights	Senior Advisor for Conscience Protection.	DH180065	03/06/2018
		Senior Advisor	DH170343	10/24/2017
	Office of Communications, Administration for Children and Families.	Senior Director, Communications and Media.	DH170289	07/07/2017
	Office of Global Affairs	Senior Policy Advisor	DH180133	05/08/2018
		Chief of Staff	DH170307	08/25/2017
	Office of Intergovernmental and External Affairs.	Advisor for External Affairs	DH170308	08/25/2017
		Regional Director Philadelphia Region III.	DH180042	02/06/2018
		Regional Director, Boston, Massachusetts, Region I.	DH180023	12/15/2017
		Regional Director, Chicago, Illinois-Region V.	DH180011	11/07/2017
		Regional Director, Denver, Colorado, Region VIII.	DH170247	09/29/2017
		Regional Director, Kansas City, Missouri, Region VII.	DH170246	10/20/2017
		Regional Director, San Francisco, California, Region IX.	DH180131	05/14/2018
		Senior Advisor	DH180092	04/16/2018
		Special Assistant	DH180162	06/08/2018
	Office of Refugee Resettlement/Office of the Director.	Policy Advisor	DH170339	10/17/2017
	Office of the Administrator	Senior Advisor (Substance Abuse)	DH170301	07/28/2017
	Office of the Assistant Secretary for Financial Resources.	Deputy Assistant Secretary, Congressional Relations.	DH180168	06/18/2018
		Director of Strategic Projects and Policy Initiatives (2).	DH180124	04/27/2018
			DH180026	12/15/2017
	Office of the Assistant Secretary for Health.	Advisor	DH180086	03/08/2018
		Deputy Chief of Staff (2)	DH180051	02/12/2018
			DH180010	11/01/2017
		Director of Communications	DH170282	07/07/2017
		Executive Director, President's Council on Fitness, Sports, and Nutrition.	DH180057	03/06/2018
		Senior Policy Advisor	DH180103	03/29/2018
		Special Advisor	DH170277	08/02/2017

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Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Assistant Secretary for Legislation.	Advisor (2)	DH180141	05/25/2018
			DH180007	11/03/2017
		Policy Advisor	DH180009	10/31/2017
		Senior Advisor	DH180084	03/22/2018
	Office of the Assistant Secretary for Public Affairs.	Assistant Speechwriter	DH180078	03/27/2018
		Deputy Director of Communications.	DH180016	11/29/2017
		Deputy Director of Speechwriting and Senior Advisor.	DH180036	12/21/2017
		Director of Communications	DH180072	03/19/2018
		Director of Digital Media	DH180158	06/11/2018
		Director of Speechwriting	DH180033	01/08/2018
		Director, Speechwriting and Editorial Services.	DH180153	05/23/2018
		Policy Advisor	DH180002	10/13/2017
		Press Assistant (Regional Media)	DH170316	08/28/2017
		Press Secretary	DH180154	05/24/2018
		Senior Advisor	DH170333	09/26/2017
		Senior Advisor and National Spokesperson.	DH180108	04/04/2018
	Office of the Deputy Secretary	Assistant	DH180038	01/16/2018
	Office of the General Counsel	Associate Deputy General Counsel (2).	DH180049	05/08/2018
			DH180163	06/13/2018
		Advisor and Legal Counsel (2)	DH170300	07/28/2017
			DH170334	09/12/2017
		Assistant	DH170327	10/23/2017
	Office of the Secretary	Advisor (2)	DH180095	03/29/2018
			DH180104	04/17/2018
		Advisor, Scheduling Operations	DH170270	08/02/2017
		Deputy Director of Advance	DH170302	08/09/2017
		Deputy Director of Scheduling	DH180128	04/30/2018
		Director of Advance	DH180166	06/21/2018
		Director of Scheduling and Advance.	DH170294	08/02/2017
		Policy Advisor (4)	DH180123	04/20/2018
			DH180175	06/08/2018
			DH180176	06/11/2018
			DH180177	06/13/2018
		Policy Advisor for Public Health and Science.	DH170288	07/05/2017
		Senior Advance Representative	DH180150	05/24/2018
		Special Assistant (5)	DH180024	01/23/2018
			DH180132	04/23/2018
			DH180160	06/01/2018
			DH180126	06/08/2018
			DH170324	09/11/2017
		Special Assistant for Advance	DH180034	12/18/2017
		Trip Coordinator	DH170271	08/02/2017
	Office of Substance Abuse and Mental Health Services Administration.	Director of Communications	DH180112	04/06/2018
DEPARTMENT OF HOMELAND SECURITY.	Domestic Nuclear Detection Office	Program Analyst	DM170253	08/17/2017
		Special Assistant	DM170269	08/30/2017
	Federal Emergency Management Agency.	Confidential Assistant	DM180067	01/30/2018
		Director, Center for Faith-Based and Neighborhood Partnerships.	DM180111	04/10/2018
		Director, Individual and Community Preparedness.	DM180098	02/20/2018
		Press Secretary	DM170275	08/29/2017
		Special Assistant (2)	DM180069	01/30/2018
			DM180147	04/06/2018
	Office of Assistant Secretary for Legislative Affairs.	Director, Legislative Affairs	DM180058	01/30/2018
		Confidential Assistant for Legislative Affairs.	DM180195	05/14/2018
		Confidential Assistant	DM170236	07/31/2017
	Office of Countering Weapons of Mass Destruction.	Director for Countering Weapons of Mass Destruction Policy and Plans.	DM180119	03/16/2018
	Office of Partnership and Engagement.	Homeland Security Advisory Council and Campaigns Coordinator.	DM180050	01/31/2018
		Law Enforcement Liaison	DM180092	02/14/2018

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Agency name	Organization name	Position title	Authorization No.	Effective date
		Business Liaison	DM170284	09/26/2017
	Office of the Assistant Secretary for Intergovernmental Affairs.	Confidential Assistant (2)	DM170239	07/31/2017
			DM170240	07/31/2017
	Office of the Assistant Secretary for Policy.	Confidential Assistant	DM180013	11/01/2017
		Special Assistant	DM180015	11/02/2017
	Office of the Assistant Secretary for Public Affairs.	Assistant Press Secretary (2)	DM180104	02/27/2018
			DM170274	09/28/2017
		Deputy Press Secretary (2)	DM180231	06/19/2018
			DM170245	08/04/2017
		Deputy Speechwriter	DM170278	09/28/2017
		Digital Director	DM180043	01/05/2018
		Director of Digital Strategy	DM180150	04/06/2018
		Press Assistant (2)	DM180083	02/12/2018
			DM180124	03/16/2018
	Office of the Assistant Secretary for Public Affairs.	Assistant Press Secretary	DM180025	11/01/2017
	Office of the Chief of Staff	Advance Representative	DM180021	11/09/2017
		Confidential Assistant (3)	DM180159	04/11/2018
			DM170264	08/29/2017
			DM170297	10/24/2017
		Deputy Director of Advance	DM180037	01/05/2018
		Deputy White House Liaison	DM180109	03/13/2018
		Special Assistant	DM180087	01/31/2018
	Office of the Executive Secretariat	Briefing Book Coordinator	DM180076	01/31/2018
		Senior Advisor	DM180200	05/09/2018
		Briefing Book Coordinator	DM170249	07/27/2017
	Office of the General Counsel	Oversight Counsel	DM170260	08/29/2017
	Office of the Secretary	Advance Representative	DM180052	01/30/2018
		Executive Director, Homeland Security Advisory Council.	DM170247	07/27/2017
	Office of the Under Secretary for National Protection and Programs Directorate.	Coordinator of Strategic Communications.	DM180068	01/31/2018
			DM180097	03/06/2018
		Director of Public Affairs		
		Legislative Advisor	DM180172	05/08/2018
		Policy Advisor	DM180070	01/30/2018
		Special Assistant	DM180060	01/23/2018
	Office of United States Citizenship and Immigration Services.	Senior Advisor	DM180055	01/30/2018
		Senior Policy Advisor	DM170277	09/28/2017
		Special Assistant (2)	DM180044	01/30/2018
			DM170287	10/05/2017
	Office of United States Customs and Border Protection.	Deputy Chief of Staff	DM180091	02/21/2018
		Special Assistant	DM180102	02/28/2018
		Staff Assistant	DM180153	04/11/2018
		Press Secretary	DM170215	08/11/2017
	Office of United States Immigration and Customs Enforcement.	Press Assistant	DM180020	01/05/2018
		Special Assistant	DM180047	01/18/2018
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of Community Planning and Development.	Senior Advisor	DU180035	01/18/2018
		Special Policy Advisor	DU180037	01/31/2018
		Deputy Assistant Secretary for Economic Development.	DU170180	09/19/2017
	Office of Congressional and Intergovernmental Relations.	Advisor for Intergovernmental Relations.	DU180042	03/13/2018
		Congressional Relations Specialist (2).	DU180062	04/06/2018
			DU180063	06/05/2018
		Deputy Assistant Secretary for Congressional Relations.	DU180051	03/19/2018
		Deputy Assistant Secretary for Intergovernmental Relations.	DU170126	08/15/2017
	Office of Fair Housing and Equal Opportunity.	Special Assistant	DU170159	08/04/2017
	Office of Faith-Based and Community Initiatives.	Director of Faith Based	DU170158	08/04/2017
	Office of Field Policy and Management.	Senior Advisor	DU170173	08/18/2017
		Regional Administrator—Region I	DU170176	09/06/2017
		Regional Administrator (4)	DU170177	09/14/2017
			DU180004	10/06/2017
			DU180008	11/09/2017
			DU180007	12/08/2017
	Office of Housing	Advisor	DU180050	04/16/2018
		Policy Advisor	DU180082	06/21/2018
		Special Assistant	DU180002	10/20/2017

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Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of Policy Development and Research.	Special Policy Advisor	DU170172	08/17/2017
	Office of Public Affairs	Assistant Press Secretary	DU180080	06/13/2018
		Deputy Assistant Secretary for Public Affairs.	DU170170	08/18/2017
		Director of Speechwriting for Program and Policy.	DU180043	03/27/2018
		Press Secretary	DU180021	01/23/2018
	Office of Public and Indian Housing	Special Assistant	DU180020	01/19/2018
	Office of the Administration	Special Assistant	DU180081	06/21/2018
		Senior Advisor	DU170165	08/22/2017
	Office of the Chief Financial Officer	Senior Advisor	DU180072	06/18/2018
	Office of the Deputy Secretary	Scheduler (2)	DU180078	06/05/2018
			DU170161	08/22/2017
		Senior Policy Advisor	DU180022	01/16/2018
		Special Assistant	DU170160	08/11/2017
	Office of the General Counsel	Attorney Advisor	DU180083	06/25/2018
	Office of the Secretary	Policy and Programs Officer	DU180068	05/17/2018
		Senior Advisor	DU170166	08/18/2017
		Special Assistant	DU170149	08/04/2017
		Special Policy Advisor	DU170153	07/19/2017
DEPARTMENT OF THE INTERIOR	Office of Assistant Secretary—Fish and Wildlife and Parks.	Senior Advisor	DI180050	04/17/2018
	Office of Assistant Secretary—Indian Affairs.	Senior Advisor (2)	DI180058	04/24/2018
			DI180005	10/23/2017
		Counsel	DI180010	11/29/2017
	Office of Assistant Secretary—Insular Areas.	Senior Advisor	DI180049	05/25/2018
	Office of Assistant Secretary—Land and Minerals Management.	Advisor (2)	DI170105	07/31/2017
			DI170106	07/31/2017
		Special Assistant	DI170116	09/14/2017
	Office of Assistant Secretary—Policy, Management and Budget.	Senior Advisor	DI170115	09/19/2017
		Field Coordinator	DI180009	11/20/2017
	Bureau of Land Management	Advisor	DI180040	06/08/2018
		Counselor	DI170097	07/06/2017
	Bureau of Ocean Energy Management.	Advisor	DI180032	03/23/2018
	Bureau of Reclamation	Advisor	DI180068	06/21/2018
		Special Assistant	DI180007	10/30/2017
	National Park Service	Senior Advisor for Congressional and Legislative Affairs.	DI180027	01/11/2018
	Office of the Solicitor	Attorney Advisor	DI180033	04/17/2018
	Secretary's Immediate Office	Advisor (2)	DI180056	05/09/2018
			DI170087	07/06/2017
		Counselor	DI180011	12/20/2017
		Deputy Director of Communications.	DI170086	07/14/2017
		Deputy Director, External Affairs	DI180046	05/30/2018
		Deputy Press Secretary	DI180019	02/06/2018
		Deputy White House Liaison	DI180035	03/08/2018
		Director of Scheduling and Advance.	DI180038	04/06/2018
		Press Secretary	DI170092	07/06/2017
		Senior Advance Representative	DI180048	04/20/2018
		Senior Advisor for Strategic Communication and Outreach.	DI170114	09/26/2017
		Senior Counsel	DI180008	11/20/2017
		Senior Deputy Director, Office of Intergovernmental and External Affairs.	DI170112	09/14/2017
		Special Assistant (2)	DI180006	01/26/2018
			DI180054	05/02/2018
		Speechwriter	DI180034	03/01/2018
	Office of United States Fish and Wildlife Service.	Advisor (2)	DI180021	01/10/2018
			DI170099	09/06/2017
DEPARTMENT OF JUSTICE	Office of Antitrust Division	Counsel (2)	DJ180049	01/31/2018
			DJ170152	07/31/2017
	Office of Civil Division	Counsel (3)	DJ180052	01/23/2018
			DJ170153	07/21/2017
			DJ170154	08/04/2017
		Senior Counsel	DJ170187	09/28/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Civil Rights Division ...	Counsel (2)	DJ170130	07/07/2017
			DJ170128	07/17/2017
		Chief of Staff and Counsel	DJ170180	10/17/2017
		Senior Counsel	DJ170173	11/02/2017
	Department of Justice	Chief of Staff and Counsel	DJ180037	01/02/2018
	Office of Environment and Natural Resources Division.	Chief of Staff and Counsel	DJ180032	01/02/2018
	Office of National Security Division	Counsel	DJ180003	11/09/2017
	Office of Justice Programs	Senior Advisor (2)	DJ180042	03/23/2018
			DJ170177	10/18/2017
		Confidential Assistant	DJ180019	11/17/2017
	Office of Legal Policy	Chief of Staff and Counsel	DJ170171	10/23/2017
		Counsel (3)	DJ170179	10/20/2017
			DJ180004	10/24/2017
			DJ180027	11/20/2017
	Office of Legislative Affairs	General Attorney	DJ180058	03/08/2018
			DJ180059	03/08/2018
		Research Assistant	DJ180099	06/21/2018
		Attorney Advisor and Intergovernmental Liaison.	DJ180024	11/22/2017
	Office of Public Affairs	Program Event Press Specialist	DJ180061	03/28/2018
		Media Affairs Specialist	DJ180036	12/12/2017
	Office of the Associate Attorney General.	Confidential Assistant (2)	DJ180044	01/23/2018
			DJ170166	09/06/2017
		Counsel	DJ170129	07/06/2017
	Office of the Attorney General	Confidential Assistant	DJ180028	01/03/2018
		Senior Policy Advisor	DJ180071	03/22/2018
		Special Assistant (3)	DJ180100	05/25/2018
			DJ180101	06/13/2018
			DJ180025	11/09/2017
		White House Liaison	DJ170172	09/15/2017
DEPARTMENT OF LABOR	Bureau of International Labor Affairs.	Special Assistant	DL170122	10/12/2017
	Office of Employee Benefits Security Administration.	Senior Advisor	DL170119	10/03/2017
	Office of Employment and Training Administration.	Chief of Staff	DL170090	09/06/2017
		Counsel	DL180097	05/14/2018
		Senior Policy Advisor (4)	DL180047	01/31/2018
			DL180101	06/08/2018
			DL180015	10/24/2017
			DL180009	11/13/2017
		Special Assistant	DL180062	04/06/2018
	Office of Mine Safety and Health Administration.	Chief of Staff	DL180061	04/27/2018
		Senior Advisor (2)	DL180099	06/08/2018
			DL170117	10/12/2017
	Office of Occupational Safety and Health Administration.	Special Assistant	DL180087	05/14/2018
	Office of Congressional and Intergovernmental Affairs.	Chief of Staff	DL180014	11/09/2017
		Confidential Assistant	DL180017	11/29/2017
		Legislative Officer (3)	DL180044	01/31/2018
			DL170097	09/08/2017
			DL170118	10/03/2017
		Senior Legislative Officer (2)	DL170099	09/14/2017
			DL170107	09/22/2017
	Office of Disability Employment Policy.	Senior Advisor	DL170115	09/19/2017
	Office of Federal Contract Compliance Programs.	Senior Advisor	DL170102	11/09/2017
	Office of Labor-Management Standards.	Senior Policy Advisor	DL180096	06/01/2018
	Office of Public Affairs	Communications Director (2)	DL180106	06/14/2018
			DL170078	08/30/2017
		Deputy Press Secretary	DL180098	06/08/2018
		Press Assistant	DL180057	03/27/2018
		Senior Advisor for Digital Strategy	DL180054	03/22/2018
		Senior Speechwriter	DL180018	12/20/2017
		Staff Assistant	DL170083	08/30/2017
	Office of Public Liaison	Special Assistant	DL180053	03/27/2018
		Public Liaison	DL180030	12/20/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Assistant Secretary for Administration and Management.	Senior Advisor	DL180024	12/20/2017
		Special Assistant (2)	DL180046	01/31/2018
			DL180027	12/21/2017
	Office of the Assistant Secretary for Policy.	Counsel and Policy Advisor	DL180085	06/13/2018
		Policy Advisor	DL170082	08/09/2017
		Senior Counsel and Policy Advisor	DL180064	04/16/2018
		Senior Policy Advisor	DL170123	10/12/2017
		Special Assistant (2)	DL170073	07/21/2017
			DL170106	09/26/2017
	Office of the Deputy Secretary	Counselor	DL180070	04/16/2018
		Confidential Assistant and Director of Scheduling.	DL180077	04/20/2018
		Special Assistant	DL180095	06/01/2018
	Office of the Secretary	Counsel	DL170087	08/09/2017
		Director of Scheduling	DL180029	01/23/2018
		Policy Advisor	DL180045	01/31/2018
		Senior Counselor	DL170098	09/11/2017
		Special Assistant (11)	DL180079	04/27/2018
			DL180088	05/08/2018
			DL180093	06/08/2018
			DL180104	06/21/2018
			DL170075	07/21/2017
			DL170095	09/11/2017
			DL170108	09/22/2017
			DL170114	09/22/2017
			DL170125	10/12/2017
			DL170121	11/02/2017
			DL170110	11/09/2017
		Staff Assistant	DL170100	09/22/2017
	Office of Veterans Employment and Training Service.	Chief of Staff	DL180081	05/08/2018
		Senior Advisor	DL180083	06/13/2018
	Office of Wage and Hour Division	Senior Policy Advisor	DL170074	08/17/2017
	Office of Women's Bureau	Chief of Staff	DL180092	05/14/2018
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.	Office of Communications	Senior Advisor/Press Secretary	NN180018	04/27/2018
		Executive Assistant	NN180019	04/27/2018
		Social Media Specialist (2)	NN180033	06/05/2018
			NN180004	11/29/2017
	Office of the Administrator	Special Assistant	NN180034	06/05/2018
	Office of the Chief Financial Officer	Policy Analyst	NN170048	08/11/2017
NATIONAL CREDIT UNION ADMINISTRATION.	National Credit Union Administration.	Director, Public and Congressional Affairs.	CU180001	12/01/2017
NATIONAL ENDOWMENT FOR THE ARTS.	National Endowment for the Arts	Public Affairs Specialist	NA180001	11/20/2017
NATIONAL ENDOWMENT FOR THE HUMANITIES.	National Endowment for the Humanities.	Executive Assistant	NH180002	04/16/2018
		White House Liaison and Chairman's Strategic Scheduler.	NH170004	07/07/2017
		Director of Communications	NH170005	08/09/2017
		Director of Congressional Affairs	NH170008	08/22/2017
		Senior Advisor	NH170006	08/24/2017
		Special Assistant	NH180001	12/06/2017
NATIONAL MEDIATION BOARD	National Mediation Board	Confidential Assistant (3)	NM180001	01/29/2018
			NM180004	01/29/2018
			NM180005	02/28/2018
NATIONAL TRANSPORTATION SAFETY BOARD.	Office of Board Members	Communications Liaison	TB180002	01/02/2018
OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.	Office of Occupational Safety and Health Review Commission.	Confidential Assistant	SH170006	11/09/2017
	Office of Commissioners	Counsel	SH180001	11/09/2017
OFFICE OF MANAGEMENT AND BUDGET.	Office of Communications	Press Secretary	BO180022	05/14/2018
		Deputy Associate Director for Communications.	BO180023	05/14/2018
		Deputy Press Secretary	BO180024	05/14/2018
	Office of Education, Income Maintenance and Labor Programs.	Confidential Assistant	BO180020	05/14/2018
	Office of the General Counsel	Confidential Assistant	BO180011	03/19/2018
	Office of General Government Programs.	Confidential Assistant	BO180013	04/13/2018
	Office of Health Division	Confidential Assistant	BO180018	05/25/2018
	Office of Legislative Affairs	Deputy for Legislative Affairs (Appropriations).	BO180014	04/13/2018

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
		Deputy for Legislative Affairs (House).	BO180017	05/08/2018
		Deputy for Legislative Affairs	BO180016	05/01/2018
		Legislative Analyst	BO180027	06/21/2018
	Office of Information and Regulatory Affairs.	Confidential Assistant	BO170083	07/21/2017
	Office of the Director	Advisor (2)	BO170081	07/10/2017
			BO170087	08/24/2017
		Confidential Assistant (2)	BO180028	06/21/2018
			BO180001	11/14/2017
		Project Coordinator	BO180012	05/02/2018
		Special Assistant	BO170092	10/17/2017
OFFICE OF NATIONAL DRUG CONTROL POLICY.	Office of Legislative Affairs	Public Affairs Specialist (Press Secretary).	QQ170010	08/17/2017
		Program Support Specialist	QQ170012	08/30/2017
		Associate Director (Legislative Affairs).	QQ170016	10/11/2017
	Office of Public Affairs	Public Affairs Specialist (Program Support).	QQ180004	03/22/2018
		Public Affairs Specialist (2)	QQ170015	09/22/2017
			QQ170017	10/11/2017
	Office of the Director	Senior Policy Advisor and White House Liaison.	QQ180005	04/24/2018
	Office of the Director	Special Advisor	QQ180006	06/21/2018
OFFICE OF PERSONNEL MANAGEMENT.	Office of Congressional, Legislative, and Intergovernmental Affairs.	Legislative Director	PM180015	03/27/2018
		Deputy Director	PM170050	09/06/2017
	Office of the Director	Executive Assistant (2)	PM180008	02/23/2018
			PM180013	12/29/2017
		Special Assistant	PM180017	03/22/2018
		Special Assistant for Advance	PM180028	05/16/2018
		White House Liaison	PM180012	02/16/2018
	Office of the General Counsel	Attorney-Advisor (General)	PM180022	04/06/2018
		Senior Counsel and Advisor	PM180020	04/20/2018
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.	Office of Intergovernmental Affairs and Public Liaison.	Deputy Assistant, United States Trade Representative for Intergovernmental Affairs and Public Engagement.	TN170016	07/10/2017
	Office of Congressional Affairs	Sr. Director for Congressional Affairs.	TN170017	07/31/2017
OFFICIAL RESIDENCE OF THE VICE PRESIDENT.	Official Residence of the Vice President.	Deputy Residence Manager	RV180001	04/06/2018
PRESIDENTS COMMISSION ON WHITE HOUSE FELLOWSHIPS.	Presidents Commission on White House Fellowships.	Assistant Director for Operations and Recruitment.	WH180001	04/12/2018
		Associate Director	WH170010	07/07/2017
SECURITIES AND EXCHANGE COMMISSION.	Office of the Chairman	Confidential Assistant	SE180003	02/07/2018
		Writer-Editor	SE180004	05/17/2018
	Office of the Division of Trading and Markets.	Director, Division of Trading and Markets.	SE180001	10/27/2017
SMALL BUSINESS ADMINISTRATION.	Office of Administration	Director of Scheduling and External Affairs.	SB180014	01/31/2018
		Management Support Specialist	SB180006	11/03/2017
		Special Assistant	SB180026	04/20/2018
		White House Liaison (2)	SB180013	01/23/2018
			SB180023	04/30/2018
	Office of Capital Access	Special Advisor	SB180027	04/27/2018
		Special Assistant	SB180030	06/08/2018
		Senior Advisor	SB180001	11/06/2017
	Office of Communications and Public Liaison.	Deputy Press Secretary/Social Media Manager.	SB180029	06/05/2018
		Press Secretary	SB170051	08/22/2017
		Senior Advisor	SB180008	11/20/2017
	Office of Congressional and Legislative Affairs.	Special Advisor	SB180021	03/16/2018
		Legislative Assistant (2)	SB180025	04/02/2018
			SB180022	04/17/2018
	Office of Field Operations	Regional Administrator for Region X.	SB170045	11/22/2017
		Regional Administrator V	SB180007	11/22/2017
		Regional Administrator, Region I	SB170066	12/05/2017
		Regional Administrator, Region II	SB180003	12/01/2017
		Regional Administrator, Region III	SB170065	02/01/2018

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
		Regional Administrator, Region IV	SB180016	02/02/2018
		Regional Administrator, Region VII	SB180005	11/22/2017
		Regional Administrator, Region VIII	SB180004	11/22/2017
		Senior Advisor	SB180017	02/20/2018
	Office of Government Contracting and Business Development.	Special Advisor	SB170052	08/04/2017
	Office of the Administrator	Senior Advisor	SB180024	04/02/2018
	Office of the General Counsel	Deputy General Counsel	SB170064	09/29/2017
SOCIAL SECURITY ADMINISTRATION.	Office of Retirement and Disability Policy.	Senior Advisor	SZ180021	01/26/2018
	Office of the Commissioner	Confidential Assistant	SZ180022	03/01/2018
DEPARTMENT OF STATE	Bureau of Arms Control, Verification, and Compliance.	Special Assistant	DS180006	11/16/2017
	Bureau of Counterterrorism	Special Assistant	DS180011	12/20/2017
	Bureau of Democracy, Human Rights and Labor.	Special Assistant	DS180042	04/06/2018
		Senior Advisor	DS180043	05/08/2018
	Bureau of Economic and Business Affairs.	Special Assistant	DS180033	03/20/2018
		Senior Advisor	DS180045	06/08/2018
	Bureau of Education and Cultural Affairs.	Special Advisor	DS180041	04/16/2018
	Bureau of European and Eurasian Affairs.	Strategic Advisor	DS180048	05/24/2018
		Special Assistant	DS170149	07/31/2017
	Bureau of International Information Programs.	Special Assistant	DS170203	10/13/2017
		Senior Advisor	DS180035	03/06/2018
	Bureau of Legislative Affairs	Legislative Management Officer	DS180054	06/21/2018
		Special Assistant (3)	DS170196	09/07/2017
			DS170207	10/11/2017
			DS180004	11/16/2017
	Bureau of Near Eastern Affairs	Deputy Assistant Secretary	DS170205	11/07/2017
	Bureau of Oceans and International Environmental and Scientific Affairs.	Senior Advisor	DS180044	05/25/2018
	Bureau of Overseas Buildings Operations.	Special Assistant	DS180007	12/11/2017
	Bureau of Public Affairs	Deputy Assistant Secretary for Strategic Communication.	DS180012	12/20/2017
	Office of Global Women's Issues	Special Assistant	DS180039	03/27/2018
	Office of Policy Planning	Senior Advisor (6)	DS180015	01/23/2018
			DS180031	03/08/2018
			DS170158	09/11/2017
			DS170193	09/19/2017
			DS170183	07/14/2017
			DS170209	09/29/2017
		Special Assistant (3)	DS180017	01/31/2018
			DS180018	02/02/2018
			DS180003	11/16/2017
		Staff Assistant	DS170208	09/29/2017
	Office of the Chief of Protocol	Staff Assistant (Visits)	DS180016	01/18/2018
		Assistant Chief of Protocol (Visits)	DS180032	02/02/2018
		Protocol Officer	DS180023	02/12/2018
		Assistant Chief of Protocol for Ceremonials.	DS180025	03/01/2018
		Chief of Staff	DS180034	03/01/2018
		Protocol Officer (Visits)(2)	DS170191	08/25/2017
			DS170198	09/08/2017
		Staff Assistant (Gifts)	DS170199	10/03/2017
	Office of the Deputy Secretary	Special Assistant	DS170190	08/30/2017
	Office of the Secretary	Advisor	DS180049	05/14/2018
		Special Assistant (2)	DS180020	01/31/2018
			DS170192	09/01/2017
		Special Assistant (Scheduler)	DS180027	02/02/2018
		Staff Assistant (Deputy Scheduler)	DS180026	02/16/2018
	Office of the United States Global Aids Coordinator.	Chief of Staff & Chief Policy Officer	DS170182	07/07/2017
		Special Assistant for Congressional Relations.	DS170206	10/18/2017
		Senior Data Analyst	DS180001	10/26/2017
	Office of the Under Secretary for Management.	Advisor	DS170181	07/14/2017
		Special Advisor	DS170186	07/21/2017
		Special Assistant (2)	DS170135	08/30/2017
			DS180014	12/18/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office to Monitor and Combat Trafficking In Persons.	Special Assistant	DS180024	02/06/2018
TRADE AND DEVELOPMENT AGENCY.	Office of the Director	Senior Advisor	TD180001	01/04/2018
DEPARTMENT OF TRANSPORTATION.	Office of the Administrator	Director of Governmental and Public Affairs.	DT180022	02/22/2018
		Director of Governmental Affairs (2).	DT180009	03/23/2018
			DT170120	07/07/2017
		Special Assistant (3)	DT170126	07/31/2017
			DT170127	08/10/2017
			DT170053	08/30/2017
	Office of the Assistant Secretary for Budget and Programs.	Special Assistant	DT180032	03/23/2018
	Office of the Assistant Secretary for Governmental Affairs.	Senior Governmental Affairs Officer (2).	DT180016	04/13/2018
			DT170141	08/17/2017
		Special Assistant	DT180042	04/27/2018
	Office of the Assistant Secretary for Transportation Policy.	Speechwriter	DT180046	04/27/2018
		Associate Director for Public Engagement.	DT170144	08/09/2017
	Office of Chief Information Officer	Special Assistant	DT180037	03/15/2018
	Office of the Executive Secretariat	Special Assistant (2)	DT180039	04/16/2018
			DT170147	08/22/2017
	Office of the General Counsel	Legal Advisor	DT170149	09/28/2017
	Immediate Office of the Administrator.	Director of Governmental, International and Public Affairs.	DT180048	05/14/2018
		Special Assistant	DT170129	08/10/2017
	Office of Communications and Legislative Affairs.	Director of Public Affairs	DT180020	02/22/2018
	Office of Public Affairs	Director of Public Affairs	DT180047	04/27/2018
		Special Assistant (3)	DT180015	02/27/2018
			DT180056	06/22/2018
			DT170124	08/16/2017
	Office of the Secretary	Senior Advisor for Policy	DT180054	06/08/2018
		Special Assistant	DT170154	10/11/2017
	Office of the Secretary	Deputy Director of Scheduling and Advance (2).	DT180027	04/24/2018
			DT180026	01/30/2018
		Special Assistant (3)	DT180034	03/23/2018
			DT180033	04/13/2018
			DT170130	09/26/2017
		Special Assistant for Advance (2)	DT180035	03/23/2018
			DT180036	03/23/2018
		Special Assistant for Scheduling and Advance (2).	DT180058	06/21/2018
			DT170137	08/10/2017
		White House Liaison	DT170143	09/06/2017
DEPARTMENT OF THE TREASURY.	Office of the Assistant Secretary (Legislative Affairs).	Senior Advisor	DY180034	01/23/2018
	Office of the Assistant Secretary (Public Affairs).	Press Assistant	DY180031	01/31/2018
		Senior Advisor	DY170141	07/14/2017
	Office of the Assistant Secretary for International Markets and Development.	Special Assistant	DY180069	05/14/2018
	Department of the Treasury	Advance Representative	DY170142	07/14/2017
		Assistant Executive Secretary (2)	DY180012	01/02/2018
			DY180013	01/02/2018
		Personal Aide	DY180057	04/05/2018
		Senior Advisor (3)	DY180033	01/31/2018
			DY180079	06/13/2018
			DY180058	04/16/2018
		Special Advisor	DY180046	02/27/2018
		Special Assistant (4)	DY180076	06/01/2018
			DY180075	06/08/2018
			DY170161	08/17/2017
			DY170173	09/29/2017
	Secretary of the Treasury	Special Assistant (Advance)(2)	DY180084	06/14/2018
			DY180085	06/14/2018
UNITED STATES INTERNATIONAL TRADE COMMISSION.	Office of Commissioner Broadbent	Confidential Assistant	TC170001	07/21/2017
DEPARTMENT OF VETERANS AFFAIRS.	Office of the Assistant Secretary for Congressional and Legislative Affairs.	Special Assistant	DV170063	07/07/2017

SCHEDULE C—Continued

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of the Assistant Secretary for Public and Intergovernmental Affairs.	Special Advisor	DV180012	01/12/2018
		Special Assistant/Deputy Press Secretary.	DV180013	01/12/2018
	Office of the Secretary and Deputy	Senior Advisor for Investigations	DV180022	03/05/2018
		Special Assistant	DV180033	05/09/2018
		Senior Advisor and Veterans Service Organization Liaison.	DV180034	06/13/2018
		Special Assistant Strategic Engagements.	DV180037	06/29/2018
		Senior Advisor Office of Accountability and Whistleblower Protection.	DV170089	10/03/2017
	Office of Veterans Benefits Administration.	Deputy Chief of Staff	DV180036	06/21/2018

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p.218.

Alexys Stanley,

Regulatory Affairs Analyst, Office of Personnel Management.

[FR Doc. 2019–15247 Filed 7–17–19; 8:45 am]

BILLING CODE 6325–39–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 15, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 108 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–165, CP2019–185.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–15295 Filed 7–17–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 18, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 15, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 109 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–166, CP2019–186.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–15293 Filed 7–17–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86368; File No. SR–EMERALD–2019–25]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

July 12, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 28, 2019, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Emerald Fee Schedule (the ''Fee Schedule'').

While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on July 1, 2019.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Exchange Rebates/Fees set forth in Section 1)a)i of the Fee Schedule to provide Members [3] a higher Simple Maker rebate of $0.50 [4] per contract executed in SPY, QQQ and IWM options for Priority Customer [5] Origin in Tiers 1, 2 and 3, instead of the rebate amount otherwise set forth in such Tiers.

Background

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [6]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has exceeded approximately 17% of the market share of executed volume of multiply-listed equity and ETF options trades.[7] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, since the Exchange launched operations on March 1, 2019, the Exchange has had less than 1% market share in any month of executed volume of multiply-listed equity & ETF options trades.[8] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees.

Proposed Rule Change

The Exchange currently assesses transaction rebates and fees to all market participants which are based upon a threshold tier structure (''Tier'') that is applicable to transaction fees. Tiers are determined on a monthly basis and are based on three alternative calculation methods, as defined in Section 1)a)ii) of the Fee Schedule. The calculation method that results in the highest Tier achieved by the Member shall apply to all Origin types by the Member. The monthly volume thresholds for each method, associated with each Tier, are calculated as the total monthly volume executed by the Member in all options classes on MIAX Emerald in the relevant Origins and/or applicable liquidity, not including Excluded Contracts,[9] (as the numerator) expressed as a percentage of (divided by) Customer Total Consolidated Volume (''CTCV'') (as the denominator). CTCV means Customer Total Consolidated Volume calculated as the total national volume cleared at The Options Clearing Corporation (''OCC'') in the Customer range in those classes listed on MIAX Emerald for the month for which fees apply, excluding volume cleared at the OCC in the Customer range executed during the period of time in which the Exchange experiences an ''Exchange System Disruption'' [10] (solely in the option classes of the affected Matching Engine).[11] In addition, the per contract transaction rebates and fees shall be applied retroactively to all eligible volume once the Tier has been reached by the Member. Members that place resting liquidity, *i.e.,* orders on the MIAX Emerald System, will be assessed the specified ''maker'' rebate or fee (each a ''Maker'') and Members that execute against resting liquidity will be assessed the specified ''taker'' fee or rebate (each a ''Taker'').[12]

Currently, transaction rebates and fees for Penny and Non-Penny classes are assessed according to the following tables:

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[4] The Exchange notes that rebates in the Fee Schedule are denoted using parentheses.

[5] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). The number of orders shall be counted in accordance with the following Interpretation and Policy .01 hereto. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[6] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[7] The Options Clearing Corporation (''OCC'') publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/market-data/volume/default.jsp.*

[8] *See id.*

[9] ''Excluded Contracts'' means any contracts routed to an away market for execution.

[10] The term ''Exchange System Disruption'' means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hour or more, during trading hours. *See* the Definitions Section of the Fee Schedule.

[11] A ''Matching Engine'' is a part of the MIAX Emerald electronic system that processes options orders and trades on a symbol-by-symbol basis. Some Matching Engines will process option classes with multiple root symbols, and other Matching Engines may be dedicated to one single option root symbol (for example, options on SPY may be processed by one single Matching Engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated Matching Engine. A particular root symbol may not be assigned to multiple Matching Engines. *See* the Definitions Section of the Fee Schedule.

[12] For a Priority Customer complex order taking liquidity in both a Penny class and non-Penny class against Origins other than Priority Customer, the Priority Customer order will receive a rebate based on the Tier achieved.

MEMBERS AND THEIR AFFILIATES IN PENNY CLASSES
[Simple/Complex/PRIME/cPRIME]

Origin	Tier	Simple		Complex #			PRIME/cPRIME ◊		
		Maker	Taker ^	Maker (contra origins ex priority customer)	Maker (contra priority customer origin)	Taker	Agency	Contra	Responder
Market Maker	1	($0.35)	$0.50	$0.10	$0.47	$0.50	$0.05	$0.05	$0.05
	2	(0.35)	0.50	0.10	0.47	0.50	0.05	0.05	0.05
	3	(0.35)	0.50	0.10	0.47	0.50	0.05	0.05	0.05
	4	(0.45)	0.48	0.10	0.47	0.50	0.05	0.05	0.05
Non-MIAX Emerald Market Maker	1	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	2	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	3	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	4	(0.25)	0.48	0.20	0.50	0.50	0.05	0.05	0.05
Firm Proprietary/Broker-Dealer	1	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	2	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	3	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	4	(0.25)	0.49	0.20	0.50	0.50	0.05	0.05	0.05
Non-Priority Customer	1	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	2	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	3	(0.25)	0.50	0.20	0.50	0.50	0.05	0.05	0.05
	4	(0.25)	0.49	0.20	0.50	0.50	0.05	0.05	0.05
Priority Customer *	1	(0.48)	0.47	(0.25)	(0.25)	(0.25)	0.00	0.05	0.05
	2	(0.48)	0.47	(0.40)	(0.40)	(0.40)	0.00	0.05	0.05
	3	(0.48)	0.47	(0.45)	(0.45)	(0.45)	0.00	0.05	0.05
	4	(0.53)	0.45	(0.50)	(0.50)	(0.50)	0.00	0.05	0.05

MEMBERS AND THEIR AFFILIATES IN NON-PENNY CLASSES
[Simple/Complex/PRIME/cPRIME]

Origin	Tier	Simple		Complex #			PRIME/cPRIME ◊		
		Maker	Taker ^	Maker (contra origins ex priority customer)	Maker (contra priority customer origin)	Taker ~	Agency	Contra	Responder
Market Maker	1	($0.45)	$0.99	$0.20	$0.86	$0.88	$0.05	$0.05	$0.05
	2	(0.45)	0.99	0.20	0.86	0.88	0.05	0.05	0.05
	3	(0.45)	0.99	0.20	0.86	0.86	0.05	0.05	0.05
	4	(0.75)	0.94	0.20	0.86	0.86	0.05	0.05	0.05
Non-MIAX Emerald Market Maker	1	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	2	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	3	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	4	(0.25)	0.94	0.20	0.88	0.88	0.05	0.05	0.05
Firm Proprietary/Broker-Dealer	1	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	2	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	3	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	4	(0.25)	0.94	0.20	0.88	0.88	0.05	0.05	0.05
Non-Priority Customer	1	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	2	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	3	(0.25)	0.99	0.20	0.88	0.88	0.05	0.05	0.05
	4	(0.25)	0.94	0.20	0.88	0.88	0.05	0.05	0.05
Priority Customer*	1	(0.85)	0.85	(0.40)	(0.40)	(0.40)	0.00	0.05	0.05
	2	(0.85)	0.85	(0.60)	(0.60)	(0.60)	0.00	0.05	0.05
	3	(0.85)	0.85	(0.70)	(0.70)	(0.75)	0.00	0.05	0.05
	4	(1.05)	0.82	(0.87)	(0.87)	(0.85)	0.00	0.05	0.05

^ Contra to Priority Customer Simple Orders, Origins ex Priority Customer Simple Orders will be charged $0.50 and Priority Customer Simple Orders will be charged $0.49 in Penny classes, and Origins ex Priority Customer Simple Orders will be charged $1.10 and Priority Customer Simple Orders will be charged $0.85 in Non-Penny classes.

* Priority Customer Complex Orders contra to Priority Customer Complex Orders are neither charged nor rebated. Priority Customer Complex Orders that leg into the Simple book are neither charged nor rebated.

~ A $0.05 Complex surcharge for Origins ex Priority Customer for Complex Orders that take liquidity from the Complex Order Book in Non-Penny classes.

For orders in a Complex Auction, Priority Customer Complex Orders will receive the Complex Taker rebate based on the tier achieved when contra to an Origin that is not a Priority Customer. Origins that are not a Priority Customer will be charged the applicable Maker fee depending on the contra, based on the tier achieved.

◊ For PRIME and cPRIME, the per contract rebate or fee for the preexisting contra-side interest that trades with the Agency side will be waived. PRIME/cPRIME Responder side interest that trades with unrelated Agency side interest trades as Taker will be subject to Simple or Complex rates, as applicable.

Notes Accompanying Tables Above

During the Opening Rotation and the ABBO uncrossing, the per contract rebate or fee will be waived for all Origins.

The Exchange proposes to amend the Exchange Rebates/Fees set forth in Section 1)a)i of the Fee Schedule to provide Members a higher Simple Maker rebate in Penny classes of $0.50 per contract executed in SPY, QQQ and IWM options for Priority Customer Origin in Tiers 1, 2 and 3, instead of the rebate amount otherwise set forth in such Tiers.

The Exchange proposes to insert the new symbol ''∇'' following the ''($0.48)'' rebate listed in Tiers 1, 2 and 3 for Simple Maker rebates in Penny classes in Section 1)a)i) of the Fee Schedule to designate a new footnote representing the proposed higher rebate of $0.50 for SPY, QQQ, and IWM. The

Exchange proposes that, following the fee table for Non-Penny classes in Section 1(a)(i) of the Fee Schedule, the Exchange will insert text describing the proposed higher rebate with new footnote ''∇'' as follows: ''Simple Maker rebate in SPY, QQQ and IWM is ($0.50) for Priority Customer Origin in Tiers 1, 2 and 3.'' The Exchanges notes that Simple Maker rebates in Penny classes for Priority Customer Origin in all options classes other than SPY, QQQ, and IWM will remain at $0.48 for Tiers 1 through 3. Further, Simple Maker rebates in Penny classes for all options classes, including options in SPY, QQQ and IWM, will remain at $0.53 for Tier 4.

The purpose of the proposed change is to incentivize Members to send Priority Customer Origin orders to the Exchange in SPY, QQQ and IWM options. The Exchange believes that the proposal to increase the Simple Maker rebate in SPY, QQQ and IWM to $0.50 for Priority Customer Origin in Tiers 1, 2 and 3 may increase the volume of Priority Customer order flow in those classes. The Exchange believes that the increased order flow will result in increased liquidity, which benefits all Exchange participants by providing more trading opportunities and tighter spreads. The proposed rebates do not apply differently to different sizes of market participants based on Tier achieved.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it is an equitable allocation of reasonable fees and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The proposal to offer higher Simple Maker rebates in SPY, QQQ and IWM options for Priority Customer Origin in Tiers 1, 2 and 3 provides for the equitable allocation of reasonable dues and fees and is not unfairly discriminatory for the following reasons. First, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15] There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has exceeded approximately 17% of the market share of executed volume of multiply-listed equity and ETF options trades.[16] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, since the Exchange launched operations on March 1, 2019, the Exchange has had less than 1% market share in any month of executed volume of multiply-listed equity & ETF options trades.[17] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees.

Second, the Exchange believes that the proposed higher Simple Maker rebate in SPY, QQQ and IWM options for Priority Customer Origin in Tiers 1, 2 and 3 is consistent with Section 6(b)(4) of the Act in that it is reasonable, equitable and not unfairly discriminatory because it applies equally to all Members for their Priority Customer Origin order flow in those options.

The Exchange operates in highly competitive market. In particular, since the Exchange launched trading on March 1, 2019, the Exchange has had less than a 1% market share in any month. Therefore, the Exchange does not possess significant pricing power in the execution of options order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain exchange transaction fees. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes the proposed change is reasonable because, as noted above, the Exchange operates in a highly competitive environment, particularly for attracting order flow that provides liquidity on the Exchange. The Exchange believes it is reasonable to provide a higher rebate for Members that trade in SPY, QQQ and IWM options in Priority Customer Origin for Tiers 1 through 3 because, to date, no Members have reached Tier 4 using the Priority Customer Maker method only (which may be different than their effective tier), and, additionally the Simple fees and rebates are essentially the same for the Priority Customer Tiers 1 through 3. The Exchange believes the proposed higher rebate is reasonable as it would provide an additional incentive for Members to provide liquidity in SPY, QQQ and IWM options, and provide meaningful added levels of liquidity, thereby contributing to the depth and market quality on the Exchange.

The Exchange believes that defining the proposed increased rebate with the new symbol ''∇'' on the Fee Schedule promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general protects investors and the public interest by creating a clear understanding of the increased rebate.

The proposed increased rebate is reasonable, equitable, and not unfairly discriminatory because it will apply similarly to all market participants who provide liquidity on the Simple Order Book for their Priority Customer Origin in SPY, QQQ and IWM options in Tiers 1, 2 and 3. All similarly situated market participants are subject to the same transaction rebate schedule, and access to the Exchange is offered on terms that are not unfairly discriminatory.

The Exchange believes that the proposal is reasonable because it will incentivize providers of SPY, QQQ, and IWM Priority Customer order flow to send that Priority Customer order flow to the Exchange in order to obtain the highest volume threshold and receive a Simple Maker rebate in a manner that enables the Exchange to improve its

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[16] *See supra* note 7.

[17] *See supra* note 7.

overall competitiveness and strengthen its market quality for all market participants.

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. As described above, the Exchange believes that the proposed change would encourage the submission of additional orders in SPY, QQQ and IWM options, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for Members.

Intra-Market Competition

The Exchange does not believe that the proposed rule change would place other market participants at the Exchange at a relative disadvantage compared to providers of SPY, QQQ, and IWM Priority Customer order flow. The Exchange believes that establishing higher rebates for these select products for Priority Customers is reasonable, equitable, and not unfairly discriminatory because these select products are generally more liquid than other option classes and the Exchange believes that the proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the proposed increased rebates would continue to incentivize market participants to provide order flow to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages Members to send orders thereby contributing to robust levels of liquidity, which benefits all market participants. The proposed higher rebates would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Inter-Market Competition

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange notes that since the Exchange launched operations on March 1, 2019, the Exchange's market share has been less than 1% in any month. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing, the Exchange does not believe its proposed increased rebate can impose any burden on competition. The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution. The Exchange also believes that the proposed change is designed to provide the public and investors with a Schedule of Fees and Rebates that is clear and consistent, thereby reducing burdens on the marketplace and facilitating investor protection.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[18] and Rule 19b–4(f)(2) [19] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EMERALD–2019–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–EMERALD–2019–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EMERALD–2019–25 and should be submitted on or before August 8, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15256 Filed 7–17–19; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

[19] 17 CFR 240.19b–4(f)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86363; File No. SR–PEARL–2019–22]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX PEARL Fee Schedule

July 12, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 28, 2019, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX PEARL Fee Schedule (the ''Fee Schedule'') to establish certain non-transaction fees applicable to participants and new members trading options on and/or using services provided by MIAX PEARL.

MIAX PEARL commenced operations as a national securities exchange registered under Section 6 of the Act [3] on February 6, 2017.[4] The Exchange adopted its transaction fees and certain of its non-transaction fees in its filing SR–PEARL–2017–10.[5]

While changes to the Fee Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on July 1, 2019.

The Exchange initially filed the proposal on March 27, 2019 (SR–PEARL–2019–12).[6] That filing was withdrawn on May 20, 2019. It is replaced with the current filing (SR–PEARL–2019–22).

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Proposal

The Exchange proposes to amend the Fee Schedule to establish certain non-transaction fees applicable to participants and new members trading options on and/or using services provided by MIAX PEARL. The Exchange initially filed the proposal on March 27, 2019, designating the proposed fees effective April 1, 2019.[7] The First Proposed Rule Change was published for comment in the **Federal Register** on April 12, 2019.[8] The proposed fee changes remained in effect until the Exchange withdrew the First Proposed Rule Change on May 20, 2019.[9] The Exchange is now re-filing the proposal to establish certain non-transaction fees applicable to market participants and new members trading options on and/or using certain services provided by the Exchange, to include additional information.

The Exchange introduced the structure of certain non-transaction fees in its filing SR–PEARL–2017–10 [10] (without proposing actual fee amounts), but also explicitly waived the assessment of any such fees for the period of time which the Exchange defined as the ''Waiver Period.'' [11] The Exchange now proposes to adopt certain non-transaction fees as described below, and thereby terminate the Waiver Period applicable to such non-transaction fees. In general, the Exchange proposes to amend the Fee Schedule to establish a one-time membership application fee for MIAX PEARL Members; [12] Application Programming Interface (''API'') Testing and Certification fees; and MIAX PEARL Member Participant Identifier (''MPID'') [13] fees.

The Exchange also proposes to amend the Fee Schedule to remove the text and application of the three-month New Member Non-Transaction Fee Waiver.[14] The Exchange adopted the three-month New Member Non-Transaction Fee Waiver in its filing SR–PEARL–2018–07.[15]

The Exchange proposes to remove the New Member Non-Transaction Fee Waiver as described below, and thereby terminate the New Member Non-Transaction Fee Waiver as it applies to all relevant fees, which would include the Monthly Trading Permit fee; Port fees; and MIAX PEARL Top of Market (''ToM'') and MIAX PEARL Liquidity Feed (''PLF'') market data fees. The Exchange also proposes to amend the Definitions section of the Fee Schedule to delete the definitions of ''New Member Non-Transaction Fee Waiver''

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f.

[4] *See* Securities Exchange Act Release No. 79543 (December 13, 2016), 81 FR 92901 (December 20, 2016) (File No. 10–227) (order approving application of MIAX PEARL, LLC for registration as a national securities exchange).

[5] *See* Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (SR–PEARL–2017–10).

[6] *See* Securities Exchange Act Release No. 85541 (April 8, 2019), 84 FR 14983 (April 12, 2019) (SR–PEARL–2019–12) (the ''First Proposed Rule Change'').

[7] *See id.*

[8] *See id.*

[9] *See* Letter from Gregory P. Ziegler, AVP and Senior Associate Counsel, MIAX PEARL, LLC, to Vanessa Countryman, Acting Secretary, Commission, dated May 17, 2019.

[10] *See supra* note 5.

[11] ''Waiver Period'' means, for each applicable fee, the period of time from the initial effective date of the MIAX PEARL Fee Schedule until such time that the Exchange has an effective fee filing establishing the applicable fee. The Exchange will issue a Regulatory Circular announcing the establishment of an applicable fee that was subject to a Waiver Period at least fifteen (15) days prior to the termination of the Waiver Period and effective date of any such applicable fee. *See* the Definitions Section of the Fee Schedule.

[12] ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of the Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[13] An MPID is a code used in the MIAX PEARL system to identify the participant to MIAX PEARL and to the participant's Clearing Member respecting trades executed on MIAX PEARL. Participants may use more than one MPID.

[14] ''New Member Non-Transaction Fee Waiver'' means the waiver of certain non-transaction fees, as explicitly set forth in specific sections of the Fee Schedule, for a new Member of the Exchange, for the waiver period. For purposes of this definition, the waiver period consists of the calendar month the new Member is credentialed to use the System in the production environment following approval as a new Member of the Exchange and the two (2) subsequent calendar months thereafter. For purposes of this definition, a new Member shall mean any Member who has not previously been approved as a Member of the Exchange. *See* the Definitions Section of the Fee Schedule.

[15] *See* Securities Exchange Act Release No. 82867 (March 13, 2018), 83 FR 12044 (March 19, 2018) (SR–PEARL–2018–07).

and ''Waiver Period'' as those definitions would no longer be applicable in accordance with this proposal to remove the Waiver Period for all remaining waived non-transaction fees, as described below, including the three-month fee waiver applicable to certain non-transaction fees for new Members of the Exchange.

MIAX PEARL Membership Application Fee

The Exchange proposes to assess a one-time membership application fee based upon the applicant's status as either an Electronic Exchange Member [16] (''EEM'') or as a Market Maker.[17] The Exchange proposes that applicants for MIAX PEARL Membership as an EEM will be assessed a one-time application fee of $500. The Exchange proposes that applicants for MIAX PEARL Membership as a Market Maker will be assessed a one-time application fee of $1,500. The difference in the proposed membership application fee to be charged to EEMs and Market Makers reflects the additional review and processing costs and effort needed for Market Maker applications. MIAX PEARL's proposed one-time membership application fees are similar to and generally lower than one-time application fees in place at the Cboe Exchange, Inc. (''Cboe'') ($3,000 for an individual applicant and $5,000 for an applicant organization) [18] and at Nasdaq ISE, LLC (''Nasdaq ISE'') ($7,500 per firm for a primary market maker, $5,500 per firm for a competitive market maker, and $3,500 per firm for an electronic market maker).[19] Below is the table for the proposed one-time membership application fee for MIAX PEARL:

Type of membership	Application fee
Electronic Exchange Member	$500.00
Market Maker	1,500.00

MIAX PEARL will assess a one-time Membership Application Fee on the earlier of (i) the date the applicant is certified in the membership system, or (ii) once an application for MIAX PEARL membership is finally denied.

Member API Testing and Certification Fee

Next, the Exchange proposes to assess an API Testing and Certification fee to Members. An API makes it possible for Member software to communicate with MIAX PEARL software applications, and is subject to Member testing with, and certification by, MIAX PEARL. API testing and certification includes, for EEMs, testing all available order types, new order entry, order management, order throughput and mass order cancellation. For Market Makers, API testing and certification also includes testing of all available quote types, quote throughput, quote management and cancellation, Aggregate Risk Manager settings and triggers, and confirmation of quotes within the trading engines.

The API Testing and Certification fees for Members are based upon the type of interface that the Member has been credentialed to use. The Exchange proposes to assess an API testing and certification fee for Members (i) initially per API for FIX,[20] MEO,[21] FXD[22] and CTD[23] in the month the Member has been credentialed to use one or more ports in the production environment for the tested API, and (ii) each time a Member initiates a change to its system that requires testing and certification. The Exchange also proposes that API Testing and Certification fees will not be assessed in situations where the Exchange initiates a mandatory change to the Exchange's System [24] that requires testing and certification.

Any Member can select any type of interface (FIX Interface, MEO Interface, FXD Interface, and/or the CTD Port) to test and certify. The Exchange proposes the following fees: Each Member who uses the FIX Interface to connect to the System will be assessed an API Testing and Certification fee of $1,000; each Member who uses the MEO Interface to connect to the System will be assessed an API Testing and Certification fee of $1,500; each Member who uses the FXD Interface to connect to the system will be assessed an API Testing and Certification fee of $500; and each Member who uses the CTD Port to connect to the system will be assessed an API Testing and Certification fee of $500.

Below is the proposed fee table for API Testing and Certification fees for Members:

Type of interface	API testing and certification fee
FIX	$1,000.00
MEO	1,500.00
FXD	500.00
CTD	500.00

API Testing and Certification Fees will be assessed (i) initially per API for FIX, MEO, FXD and CTD in the month the Member has been credentialed to use one or more ports in the production environment for the tested API, and (ii) each time a Member initiates a change to its system that requires testing and certification. API Testing and Certification Fees will not be assessed in situations where the Exchange initiates a mandatory change to the Exchange's system that requires testing and certification.

[16] ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100. *See* the Definitions Section of the Fee Schedule.

[17] ''Market Maker'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. *See* Exchange Rule 100. *See* the Definitions Section of the Fee Schedule.

[18] *See* Cboe Fees Schedule, p. 12, Cboe Trading Permit Holder Application Fees.

[19] *See* Nasdaq ISE, Options Rules, Options 7, Pricing Schedule, Section 9. Legal and Regulatory A. Application.

[20] ''FIX Interface'' means the Financial Information Exchange interface for certain order types as set forth in Exchange Rule 516. *See* Exchange Rule 100. *See* the Definitions Section of the Fee Schedule.

[21] ''MEO Interface'' means a binary order interface for certain order types as set forth in Rule 516 into the MIAX PEARL System. *See* Exchange Rule 100. *See* the Definitions Section of the Fee Schedule.

[22] ''FXD Interface'' or ''FIX Drop Copy Port'' means a messaging interface that provides a copy of real-time trade execution, trade correction and trade cancellation information to FIX Drop Copy Port users who subscribe to the service. FXD Port users are those users who are designated by an EEM to receive the information and the information is restricted for use by the EEM only. *See* the Definitions Section of the Fee Schedule.

[23] ''CTD Port'' or ''Clearing Trade Drop Port'' provides an Exchange Member with a real-time clearing trade updates. The updates include the Member's clearing trade messages on a low latency, real-time basis. The trade messages are routed to a Member's connection containing certain information. The information includes, among other things, the following: (i) Trade date and time; (ii) symbol information; (iii) trade price/size information; (iv) Member type (for example, and without limitation, Market Maker, Electronic Exchange Member, Broker-Dealer); and (v) Exchange MPID for each side of the transaction, including Clearing Member MPID. *See* the Definitions Section of the Fee Schedule.

[24] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

Non-Member API Testing and Certification Fee

The Exchange proposes to assess an API Testing and Certification fee for Third Party Vendors,[25] Service Bureaus [26] and other non-Members (i) initially per API for FIX, MEO, FXD, and CTD in the month the non-Member has been credentialed to use one or more ports in the production environment for the tested API, and (ii) each time a Third Party Vendor, Service Bureau, or other non-Member initiates a change to its system that requires testing and certification. The Exchange also proposes that API Testing and Certification fees will not be assessed in situations where the Exchange initiates a mandatory change to the Exchange's System that requires testing and certification.

The Exchange's proposed API Testing and Certification fees for non-Members are based upon the type of interface used by the non-Member to connect to the Exchange—the FIX Interface, the MEO Interface, the FXD Interface, and/or the CTD Port. Any non-Member can select any type of interface (FIX Interface, MEO Interface, FXD Interface, and/or the CTD Port) to test and certify. As with Members, an API makes it possible for third party vendors' and Service Bureaus' software to communicate with MIAX PEARL software applications, and is subject to testing with, and certification by, MIAX PEARL. The higher proposed fee charged to non-Members reflects the greater amount of time spent by MIAX PEARL employees testing and certifying non-Members. It has been MIAX PEARL's experience that Member testing takes less time than non-Member testing because Members have more experience testing these systems with exchanges; generally fewer questions and issues arise during the testing and certification process. Also, because Third Party Vendors and Service Bureaus are redistributing data and reselling services to other Members and market participants, the number and types of scenarios that need to be tested are more numerous and complex than those tested and certified for a single Member.

The Exchange proposes the following fees: Each non-Member who uses the FIX Interface to connect to the System will be assessed an API Testing and Certification fee of $1,200; each non-Member who uses the MEO Interface to connect to the System will be assessed an API Testing and Certification fee of $2,000; each non-Member who uses the FXD Interface to connect to the system will be assessed an API Testing and Certification fee of $600; and each non-Member who uses the CTD Port to connect to the system will be assessed an API Testing and Certification fee of $600.

Below is the proposed fee table for API Testing and Certification fees for non-Members:

Type of interface	API testing and certification fee
FIX	$1,200.00
MEO	2,000.00
FXD	600.00
CTD	600.00

API Testing and Certification Fees for Third Party Vendors, Service Bureaus and other non-Members will be assessed (i) initially per API for FIX, MEO, FXD, and CTD in the month the non-Member has been credentialed to use one or more ports in the production environment for the tested API, and (ii) each time a Third Party Vendor, Service Bureau, or other non-Member initiates a change to its system that requires testing and certification. API Testing and Certification Fees will not be assessed in situations where the Exchange initiates a mandatory change to the Exchange's system that requires testing and certification.

MPID Fees

The Exchange proposes to assess monthly MPID fees to Members based upon the type of MPID. MPID fees are assessed for assigning and managing these identifiers for each Member. The Exchange proposes that Members will be assessed a monthly MPID fee of $125 for each FIX MPID and Members will be assessed a monthly MPID fee of $125 for each MEO MPID. MPIDs allow the Exchange to provide additional services to its Members, including customer reporting, monitoring and risk protection services, down at the MPID level. MPIDs provide Members the ability to segment their business operations in a manner that can be tailored to their business needs, as well as receive certain additional administrative and operational services provided by the Exchange.

The Exchange also proposes to introduce a cap on the amount of MPID fees that can be assessed by the Exchange to a Member of $500 per month, regardless of the actual number of EEM or MEO MPIDs assigned to such Member. The Exchange believes that establishing a monthly cap on MPID fees will provide Members greater flexibility to accommodate their varying business models and customer configurations, as many Members often request multiple MPIDs from the Exchange, and the Exchange does not want MPID costs to serve as a barrier for requesting multiple MPIDs. The Exchange notes that this fee cap is similar to the MPID fee cap assessed by the Exchange's affiliate, Miami International Securities Exchange, LLC (''MIAX'').[27]

Below is the proposed MPID fee table:

Type of MPID	Monthly MPID fees
FIX MPID	$125.00
MEO MPID	125.00

MPID fees are capped at $500.00 per month per Member.

New Member Non-Transaction Fee Waiver

The Exchange proposes to remove the New Member Non-Transaction Fee Waiver from the Fee Schedule. The New Member Non-Transaction Fee Waiver waived the assessment of a fee for a Trading Permit, Port, ToM or PLF market data feed for a new Member of the Exchange for the first calendar month during which the new Member was approved as a Member and was credentialed to use the System in the production environment, and for the two (2) subsequent calendar months thereafter.

[25] Third party vendors are subscribers of MIAX's market and other data feeds, which they in turn use for redistribution purposes. Third party vendors do not provide connectivity and therefore are not subject to Network testing and certification. *See* the Definitions Section of the Fee Schedule.

[26] ''Service Bureau'' means a technology provider that offers and supplies technology and technology services to a trading firm that does not have its own proprietary system. *See* the Definitions Section of the Fee Schedule.

[27] *See* Securities Exchange Act Release No. 82823 (March 7, 2018), 83 FR 10935 (March 13, 2018) (SR–MIAX–2018–09).

The Exchange initially waived certain non-transaction fees for new Members in order to attract new business and encourage Members to use the Exchange. The Exchange now believes that the New Member Non-Transaction Fee Waiver is no longer necessary since the MIAX PEARL market is established and MIAX PEARL no longer needs to rely on such waivers to attract market participants.

The Exchange notes that any Member who began receiving the New Member Non-Transaction Fee Waiver prior to the filing of this proposal, will continue to receive that benefit for the first calendar month during which they were approved as a Member and were credentialed to use the System in the production environment, and for the two (2) subsequent calendar months thereafter.

Applicability to and Impact on Participants [28]

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [29]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 16% market share.[30] Therefore, no exchange possesses significant pricing power. More specifically, as of June 2019, the Exchange has less than 5% market share of executed volume of multiply-listed equity & ETF options trades.[31] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products, or shift order flow, in response to fee changes. Accordingly, competitive forces constrain the Exchange's ability to set its fees for various products, services and transactions.

The proposed adoption of certain non-transaction fees would be applied uniformly to all market participants. Further, as there are currently 16 registered options exchanges competing for order flow with no single exchange accounting for more than approximately 16% of market share, the Exchange cannot predict with certainty whether any participant is planning to become a Member or utilize any of the services that the Exchange is planning to establish fees for and thus would be subject to the proposed fees.

The Exchange has issued a Regulatory Circular announcing the establishment of the aforementioned fees that were subject to the Waiver Period at least 15 days prior to the termination of the Waiver Period and effective date of the applicable fee.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [32] in general, and furthers the objectives of Section 6(b)(4) of the Act [33] in particular, in that it is an equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers. Moreover, the Exchange believes that its proposal complies with Commission guidance on SRO fee filings that the Commission Staff issued on May 21, 2019.[34]

The Exchange believes that the proposed change to eliminate the waiver of the non-transaction fees described above is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options transaction and non-transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [35]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options transaction services. The Exchange is one of several options venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. Competing options exchanges offer complex order functionality, with varying pricing schedules. The Exchange believes its proposed fees are reasonable and well within the range of non-transaction fees assessed among other exchanges, including the Exchange's affiliate, MIAX.[36]

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.[37]

[28] On May 21, 2019, the SEC Division of Trading and Markets (the ''Division'') issued fee filing guidance titled ''Staff Guidance on SRO Rule Filings Relating to Fees'' (''Guidance''). Within the Guidance, the Division noted, among other things, that the purpose discussion should address ''how the fee may apply differently (*e.g.,* additional cost vs. additional discount) to different types of market participants (*e.g.,* market makers, institutional brokers, retail brokers, vendors, etc.) and different sizes of market participants.'' *See* Guidance (available at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees*). The Guidance also suggests that the purpose discussion should include numerical examples. Where possible, the Exchange is including numerical examples. In addition, the Exchange is providing data to the Commission in support of its arguments herein. The Guidance covers all aspects of a fee filing, which the Exchange has addressed throughout this filing.

[29] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[30] The Options Clearing Corporation (''OCC'') publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/market-data/volume/default.jsp.*

[31] *See id.*

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78f(b)(4) and (5).

[34] *See* Guidance, *supra* note 28.

[35] NetCoalition v. SEC, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[36] *See* the MIAX Fee Schedule.

[37] While MIAX PEARL has not charged certain non-transaction fees as described above, to date, the Exchange perceives no regulatory, structure, or cost impediments to market participants shifting order flow away from it as a result of this rule change. *See* Guidance, *supra* note 28. In particular, the Exchange notes that these examples of shifts in liquidity and market share, along with many others, have occurred within the context of market participants' existing duties of Best Execution and obligations under the Order Protection Rule under Regulation NMS.

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than approximately 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[38] Therefore, no exchange possesses significant pricing power. More specifically, as of June 2019, the Exchange had less than 5% market share of executed volume of multiply-listed equity & ETF options trades.[39] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products, or shift order flow, in response to fee changes. Accordingly, competitive forces constrain the Exchange's ability to set its fees for various products, services and transactions.

Further, the Exchange no longer believes it is necessary to waive these fees to attract market participants to the MIAX PEARL market since this market is now established and MIAX PEARL no longer needs to rely on such waivers to attract market participants. The Exchange believes that the proposed changes are equitable and not unfairly discriminatory because the elimination of the non-transaction fees will uniformly apply to all Exchange participants based on market participant type.

The Exchange believes its one-time membership application fees are reasonable, equitable and not unfairly discriminatory. As described above, the one-time application fees are similar and generally lower than application fees in place at other options exchanges,[40] and are designed to recover costs associated with the processing of such applications. The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory that Market Maker applicants are charged slightly more than EEM applicants because of the additional costs involved in processing a Market Maker's application.

The Exchange believes it is reasonable, equitable, and not unfairly discriminatory to begin to assess API Testing and Certification fees for both Members and non-Members. The Exchange believes the proposed API Testing and Certification fees are a reasonable allocation of its costs and expenses among its Members and non-Members using its facilities since it is recovering the costs associated with providing such infrastructure testing and certification services.

MIAX PEARL believes it is reasonable, equitable and not unfairly discriminatory to assess different API Testing and Certification fees to Members and non-Members. The higher fee charged to non-Members reflects the greater amount of time spent by MIAX PEARL employees testing and certifying non-Members. It has been MIAX PEARL's experience that Member testing takes less time than non-Member testing because Members have more experience testing these systems with exchanges; generally fewer questions and issues arise during the testing and certification process. Also, with respect to API testing and certification, because Third Party Vendors and Service Bureaus are redistributing data and reselling services to other Members and market participants the number and types of scenarios that need to be tested are more numerous and complex than those tested and certified for Members.

The Exchange believes its proposal to assess monthly MPID fees to Members based upon the type of MPID is reasonable, equitable and not unfairly discriminatory because the proposed fees apply to all Members assigned MPIDs equally and will allow the Exchange to assess fees for assigning and maintaining such services. The Exchange believes its proposal is a reasonable allocation of fees because MPIDs provide Members the ability to segment their business operations in a manner that can be tailored to their business needs, as well as receive certain additional administrative and operational services provided by the Exchange. The proposed monthly MPID fees are equitable and not unfairly discriminatory because the proposed MPID fees will allow the Exchange to continue to maintain and enhance value-added services, including reporting of relevant trade information through enhanced reporting tools and provide ongoing services to customers that are assigned each MPID. The Exchange also notes that Members are not required to purchase multiple MPIDs. As of June 2019, the Exchange had 41 Members (including affiliates of Members) that have at least 1 MPID each. Of those 41 Members, 20 Members have multiple MPIDs. Further, of the 20 Members with multiple MPIDs, only 8 of those Members have more than 4 MPIDs each. Accordingly, with the proposed fee cap of $500, those 8 Members with the greatest number of MPIDs would benefit from the proposed fee cap.

The Exchange also believes that its proposal to establish a fee cap for Members on MPID fees is reasonable, equitable, and not unfairly discriminatory. The proposal to cap the total amount of MPID fees that can be assessed upon a Member to a maximum of $500 per month is designed to promote just and equitable principles of trade by encouraging Members to configure their MPID assignments with greater granularity and for MPID costs to not serve as a barrier for requesting multiple MPIDs. Because any Member is eligible to take advantage of the fee cap, the Exchange believes the fee cap is fair and equitable and not unreasonably discriminatory because it applies equally to all Members, and access to such fee cap is offered on terms that are not unfairly discriminatory.

The Exchange believes that the proposal to remove the New Member Non-Transaction Fee Waiver is reasonable, equitable, and not unfairly discriminatory because the removal of the New Member Non-Transaction Fee Waiver applies equally to all new Members of the Exchange. The Exchange initially waived certain non-transaction fees for new Members in order to attract new business and encourage Members to join the Exchange. The Exchange believes that the New Member Non-Transaction Fee Waiver is no longer necessary since the MIAX PEARL market is established and MIAX PEARL no longer relies on such waivers to attract market participants. Further, the proposed rule change will not apply to any new Member who began receiving the New Member Non-Transaction Fee Waiver prior to the filing of this proposal and will continue to receive that benefit for the first calendar month during which they were approved as a Member and were credentialed to use the System in the production environment, and for the two (2) subsequent calendar months thereafter.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees for services and products, in addition to order flow, to remain competitive with other exchanges. The Exchange believes that the proposed changes reflect this competitive environment.

[38] The Options Clearing Corporation (''OCC'') publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/market-data/volume/default.jsp.*

[39] *See id.*

[40] *See supra* notes 18 and 19.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX PEARL 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.

Intra-Market Competition

The Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. Unilateral action by MIAX PEARL in the assessment of certain non-transaction fees for services provided to its Members and others using its facilities will not have an impact on competition. As a more recent entrant in the already highly competitive environment for equity options trading, MIAX PEARL does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Act. MIAX PEARL's proposed non-transaction fee levels, as described herein, are comparable to fee levels charged by other options exchanges for the same or similar services, including those fees assessed by its affiliate, MIAX.

The Exchange believes that the proposed non-transaction fees do not place certain market participants at a relative disadvantage to other market participants because the pricing is associated with costs to the Exchange of the relevant fee being proposed. The proposed non-transaction fees do not apply unequally to different size market participants, but instead would allow the Exchange to recoup some of its costs in reviewing and processing Market Maker and EEM membership applications; costs for API testing and certification for Members and non-Members to ensure proper functioning of all available order types, new order entry, order management, order throughput and mass order cancellation (as well as, for Market Makers, all available quote types, quote throughput, quote management and cancellation, Aggregate Risk Manager settings and triggers, and confirmation of quotes within the trading engines); and costs associated with assigning and managing MPIDs for Members to ensure proper reporting, monitoring and risk protection services for customers. Accordingly, the proposed non-transaction fees do not favor certain categories of market participants in a manner that would impose a burden on competition.

Further, the Exchange believes that the proposed rule change will promote transparency by making it clear to Members and non-Members the fees that MIAX PEARL will assess for Membership application to MIAX PEARL, API testing and certification, and MPID fees, as well as the cap on MPID fees for EEMs. This will permit Members and non-Members to more accurately anticipate and account for non-transactional costs, which promotes consistency.

Inter-Market Competition

The Exchange believes the proposed non-transaction fees do not place an undue burden on competition on other SROs that is not necessary or appropriate. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing options venues if they deem fee levels at a particular venue to be excessive. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% market share. Therefore, no exchange possesses significant pricing power in the execution of multiply-listed and ETF options order flow. As of June 2019, to date, the Exchange had less than 5% market share and the Exchange believes that the ever-shifting market share among exchanges from month to month demonstrates that market participants can discontinue or reduce use of certain categories of products, or shift order flow, in response to fee changes. In such an environment, the Exchange must continually adjust its fees and fee waivers to remain competitive with other exchanges and to attract order flow to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[41] and Rule 19b–4(f)(2)[42] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2019–22 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–PEARL–2019–22. 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

[41] 15 U.S.C. 78s(b)(3)(A)(ii).

[42] 17 CFR 240.19b–4(f)(2).

submissions should refer to File Number SR–PEARL–2019–22 and should be submitted on or before August 8, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15254 Filed 7–17–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86365; File No. SR–NYSENAT–2019–16]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates To Reduce the Adding Average Daily Volume Required for ETP Holders To Qualify for the Adding Tier 1 Fees

July 12, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 1, 2019, NYSE National, Inc. (''NYSE National'' 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 its Schedule of Fees and Rebates to reduce the adding average daily volume required for ETP Holders to qualify for the Adding Tier 1 fees. The Exchange proposes to implement the rule change on July 1, 2019. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Schedule of Fees and Rebates (''Fee Schedule'') to reduce the amount of average daily volume (''ADV'') as a percentage of US consolidated ADV (''CADV'') that an ETP Holder must submit to the Exchange (*i.e.,* Adding ADV) in order to qualify for the Adding Tier 1 fees. Specifically, the Exchange proposes to lower the requirement for the first of the two ways to qualify for the Adding Tier 1 credit from an adding ADV as a percentage of CADV of 0.20% or more to an adding ADV as a percentage of CADV of 0.15% or more.

The Exchange proposes to implement the rule change on July 1, 2019.

Background

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[4]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.''[5] Indeed, equity trading is currently dispersed across 13 exchanges,[6] 31 alternative trading systems,[7] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 18% of the market share of executed volume of equity trades (whether excluding or including auction volume).[8] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, in June 2019, the Exchange had 1.2% market share of executed volume of equity trades (excluding auction volume).[9] The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange utilizes a ''taker-maker'' or inverted fee model to attract orders that provide liquidity at the most competitive prices. Under the taker-maker model, offering rebates for taking liquidity increases the likelihood that market participants will send orders to the Exchange to trade with liquidity providers' orders. This increased taker order flow provides an incentive for market participants to send orders that provide liquidity. The Exchange charges fees for order flow that provides liquidity. These fees are reasonable due to the additional marketable interest (in part attracted by the exchange's rebate to remove liquidity) with which those order flow providers can trade.

The Exchange sets forth the fees it charges for adding liquidity in four Adding Tiers that establish minimum quoting or volume requirements that an ETP Holder must satisfy in order to be eligible for specific corresponding fees. These quoting and volume requirements are based on the type of liquidity (*i.e.,*

[43] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (S7–10–04) (Final Rule) (''Regulation NMS'').

[5] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[6] *See* Cboe Global Markets, U.S. Equities Market Volume Summary (June 28, 2019), available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[7] *See* FINRA ATS Transparency Data (June 3, 2019), *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* Although 54 alternative trading systems were registered with the Commission as of May 31, 2019, only 31 are currently trading. A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[8] *See* Cboe Global Markets U.S. Equities Market Volume Summary (June 28, 2019), available at *http://markets.cboe.com/us/equities/market_share/.*

[9] *See id.*

adding, taking, displayed, non-displayed, BBO setting, or MPL) and the type of security (*i.e.,* whether it is a Tape A, B or C security). In addition, the Exchange offers two ''step up'' Adding Tiers that do not have quoting or minimum volume requirements but require ETP Holders to provide additional incremental liquidity, thus ''stepping up'' their liquidity provision, in order to qualify for better pricing based on smaller amounts of liquidity than are required to qualify for Adding Tiers 1–3. The different tiers are designed to provide an incentive for order flow providers to add liquidity on the Exchange because the fees are lower for the tiers that have higher quoting or volume requirements. ETP Holders that do not send order flow to the Exchange to qualify for the Adding Tier rates would receive the rates set forth under item A (General Rates) of the Fee Schedule.

To respond to this competitive environment, the Exchange proposes to adjust its pricing to reduce the adding ADV requirement ETP Holders must supply in order to qualify for the Adding Tier 1 fees. The Exchange's market share of intraday trading (*i.e.,* excluding auctions) declined from 1.3% for the month of May 2019 to 1.2% for the month of June 2019.[10] The proposed fee change is designed to attract additional order flow to the Exchange by making it easier to qualify for the Adding Tier 1 rates.

Proposed Rule Change

As described in more detail below, in order to qualify for the Adding Tier 1 fees, an ETP Holder must be quoting at a price that is equal to the National Best Bid (''NBB'') and National Best Offer (''NBO,'' together the ''NBBO'') a specified percentage of the time, in a specific number of securities and must have an adding ADV as a percentage of CADV of 0.20% or more. The Exchange proposes to lower the ADV percentage requirement that an ETP Holder must satisfy in order to qualify for the Adding Tier 1 rates. Without having a view of ETP Holder's activity on other markets and off-exchange venues, the Exchange believes that this reduction of the adding ADV requirement would be significant enough to incentivize market participants to increase their quoting on the Exchange to meet the new lower requirement, and thus be eligible for lower fees, and submit additional adding liquidity to the Exchange.

Adding Tier 1

Under current Adding Tier 1, ETP Holders that add liquidity to the Exchange in securities with a per share price of $1.00 or more and that:

(i) quote at the NBBO [11] at least 5% of the time in 950 or more securities on an average daily basis, calculated monthly, and have an average daily volume (''ADV'') of adding liquidity as a percentage of US consolidated ADV (''CADV'') of 0.20% or more, or

(ii) quote at the NBBO at least 5% of the time in 2,450 or more securities on an average daily basis, calculated monthly, and have an ADV of adding liquidity as a percentage of US CADV of 0.10% or more, are charged the following fees:

- $0.0008 per share for adding displayed orders in Tape B and C securities and $0.0011 per share in Tape A securities;
- $0.0008 per share for orders that set a new Exchange BBO in Tape B and C securities and $0.0011 per share in Tape A securities;
- $0.0010 per share for adding non-displayed orders in Tape B and C securities and $0.0013 per share in Tape A securities; and
- $0.0005 per share for MPL orders.

The Exchange proposes to amend the adding ADV requirements for the first of the two alternative methods described in (i) above to qualify for the tier by reducing the percentage from 0.20% or more to 0.15% or more. As proposed, the first alternative would require ETP Holders to quote at least 5% of the time at the NBBO in 950 or more securities on an average daily basis, calculated monthly, and have an ADV of adding liquidity as a percentage of CADV of 0.15% or more (as opposed to 0.20% or more). The fees charged under the Adding Tier 1 would not change.

Application of Proposed Fee Change

The proposed rule change is designed to provide order flow providers with an incentive to route liquidity-providing order flow to the Exchange. As described above, ETP Holders with liquidity-providing order flow have a choice of where to send that order flow. The Exchange believes that if it reduces the requirements to qualify for tiers that have lower fees, more ETP Holders will choose to route their liquidity-providing order flow to the Exchange to qualify for those tiers. The Exchange cannot predict with certainty how many ETP Holders would avail themselves of this opportunity, but believes that as many as 9 ETP Holders could qualify for these tiers if they so choose.[12] Additional liquidity-providing order flow benefits all market participants because it provides greater execution opportunities on the Exchange.

For example, assume an ETP Holder quotes at least 5% of the NBBO in 975 securities on an average daily basis, calculated monthly, and averages an ADV of 9 million shares of adding liquidity in a month where a billing month of US CADV is 7.2 billion, or 0.125% of CADV. Prior to the proposed change, that ETP Holder would fall short of the requirement for Tier 1, and would have instead qualified for Adding Tier 3. With this proposed change, this ETP Holder would now be eligible for Adding Tier 1 fees, which, except for MPL Adding fees, are lower than the Adding Tier 3fees [sic]. The Exchange believes that charging lower fees would create an incentive for liquidity providers to direct order flow to the Exchange, which in turn would create additional execution opportunities for all market participants.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its

[10] *See id.*

[11] *See* footnote ** in the current Fee Schedule.

[12] In the month of June 2019, 9 ETP Holders had an Adding ADV of at least 0.025%.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) & (5).

broader forms that are most important to investors and listed companies.'' [15]

As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [16] Indeed, equity trading is currently dispersed across 13 exchanges,[17] 31 alternative trading systems,[18] and numerous broker-dealer internalizers and wholesalers. Based on publicly-available information, no single exchange has more than 18% of the market share of executed volume of equity trades (whether excluding or including auction volume).[19] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, in June 2019, the Exchange had 1.2% market share of executed volume of equity trades (excluding auction volume).[20]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange, ETP Holders can choose from any one of the 13 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide displayed liquidity on an exchange.

Given this competitive environment, the proposal represents a reasonable attempt to attract additional order flow to the Exchange by making it easier to qualify for the Adding Tier 1 rates. As noted, the Exchange's market share of intraday trading (*i.e.,* excluding auctions) declined from 1.3% for the month of May 2019 to 1.2% for the month of June 2019.[21] The Exchange believes that the proposal represents a reasonable attempt to encourage the submission of additional liquidity to a national securities exchange, thus promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders from the substantial amounts of liquidity present on the Exchange. All ETP Holders would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes its proposal equitably allocates its fees among its market participants. The Exchange is not proposing to adjust the amount of the Adding Tier 1 fees, which will remain at the current level for all market participants. Rather, the proposal would continue to encourage ETP Holders to send orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The Exchange believes that, for the reasons discussed above, lowering the adding ADV requirement would make it easier for current and new liquidity providers to qualify for the Adding Tier 1 fees, thereby encouraging submission of additional liquidity to the Exchange. The proposed change will thereby encourage the submission of additional liquidity to a national securities exchange, thus promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders from the substantial amounts of liquidity present on the Exchange. All ETP Holders would benefit from the greater amounts of liquidity that will be present on the Exchange, which would provide greater execution opportunities.

The Exchange notes that there are currently 2 ETP Holders qualifying for Adding Tier 1 and that, based on current participation on the Exchange, no additional firms would initially qualify with the lower requirements. Without having a view of an ETP Holder's activity on other markets and off-exchange venues, the Exchange believes the proposed lower adding ADV requirement would provide an incentive for market participants to increase the orders they send to the Exchange in order to meet the new lower requirement and submit additional adding liquidity to the Exchange. In addition, based on the profile of liquidity-providing firms generally, the Exchange believes that 9 firms could qualify for these tiers if they choose to direct order flow to, and increase quoting on, the Exchange.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal constitutes an equitable allocation of fees because all similarly situated ETP Holders and other market participants would be charged the same rates. Moreover, the proposed change is equitable because all qualifying ETP Holders that add liquidity to the Exchange and quote at the NBBO in Adding Tier 1 would be eligible for the fee by satisfying the lowered threshold, and because the lower threshold would apply equally to all similarly situated ETP Holders. The Exchange further believes that the proposed changes would not permit unfair discrimination among ETP Holders because the tiered rates are available equally to all ETP Holders. As described above, in today's competitive marketplace, order flow providers have a choice of where to direct liquidity-providing order flow, and while only 2 ETP Holders have qualified to date for these rates, the Exchange believes there are additional ETP Holders that could qualify if they chose to direct their order flow to the Exchange.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. In the prevailing competitive environment, member organizations are free to disfavor the Exchange's pricing if they believe that alternatives offer them better value.

The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The Exchange believes that the proposal does not permit unfair discrimination because the proposal would be applied to all similarly situated ETP Holders and other market participants would be charged the same rates.

The Exchange further believes that the proposal does not permit unfair discrimination because the Exchange will be making the Adding Tier 1 rates available to all ETP Holders on an equal basis. Accordingly, no ETP Holder already operating on the Exchange would be disadvantaged by this allocation of fees. For the same reasons, the Exchange believes that the proposal would not permit unfair discrimination among ETP Holders. The Exchange believes that the proposed change is not unfairly discriminatory because all qualifying ETP Holders that add liquidity to the Exchange and quote at the NBBO in Adding Tier 1 would be eligible for the fee by satisfying the lowered threshold, and because the

[15] *See* Regulation NMS, 70 FR at 37499.

[16] *See* Transaction Fee Pilot, 84 FR at 5253.

[17] *See* Cboe Global Markets, U.S. Equities Market Volume Summary (June 28, 2019), available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[18] *See* FINRA ATS Transparency Data (June 3, 2019), *available at https://otctransparency.finra.org/otctransparency/AtsIssueData.* Although 54 alternative trading systems were registered with the Commission as of May 31, 2019, only 31 are currently trading. A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[19] *See* Cboe Global Markets U.S. Equities Market Volume Summary (June 28, 2019), available at *http://markets.cboe.com/us/equities/market_share/.*

[20] *See id.*

[21] *See id.*

lower thresholds would apply equally to all similarly situated ETP Holders.

The Exchange further believes that the proposed changes would not permit unfair discrimination among ETP Holders because the tiered rates are available equally to all ETP Holders. As described above, in today's competitive marketplace, order flow providers have a choice of where to direct liquidity-providing order flow, and while only 2 ETP Holders currently are qualified for these rates, the Exchange believes there are additional ETP Holders that could qualify if they chose to direct their order flow to the Exchange.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[22] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange by making it easier for liquidity providers to qualify for the Adding Tier 1 fees, thereby increasing the likelihood that market participants will send orders to the Exchange to trade with the liquidity providers' orders and thus promoting market depth, price discovery and transparency and enhancing order execution opportunities for ETP Holders. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [23]

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange by reducing the amount of adding ADV an ETP Permit holder is required to supply for the Adding Tier 1. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages ETP Holders to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants. The proposed reduced requirement would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. The Exchange notes that Exchange's market share of intraday trading (excluding auctions) declined from 1.3% for the month of May 2019 to 1.2% for the month of June 2019.[24] In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

The Exchange believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [25] of the Act and subparagraph (f)(2) of Rule 19b–4 [26] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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) [27] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2019–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2019–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal offices 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

[22] 15 U.S.C. 78f(b)(8).

[23] Regulation NMS, 70 FR at 37498–99.

[24] *See* note 10, *supra.*

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(2).

[27] 15 U.S.C. 78s(b)(2)(B).

to make available publicly. All submissions should refer to File Number SR–NYSENAT–2019–16, and should be submitted on or before August 8,2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15257 Filed 7–17–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86364; File No. SR–ICEEU–2019–013]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Changes Related to the ICE Clear Europe Revised Recovery Plan

July 12, 2019.

I. Introduction

On May 10, 2019, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change related to its recovery plan. The proposed rule change was published for comment in the **Federal Register** on May 28, 2019.[3] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

As a ''covered clearing agency,''[4] ICE Clear Europe is required to, among other things, ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which . . . includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.''[5] The Commission has previously clarified that it believes that such recovery and wind-down plans are ''rules'' within the meaning of Exchange Act Section 19(b) and Rule 19b–4 thereunder because such plans would constitute changes to a stated policy, practice, or interpretation of a covered clearing agency.[6] Accordingly, a covered clearing agency, such as ICE Clear Europe, is required to file its plans for recovery and orderly wind-down with the Commission.[7]

ICE Clear Europe's current recovery plan (''Existing Recovery Plan'') was approved by the Commission on July 17, 2018.[8] Recently, ICE Clear Europe has proposed changes to its rules concerning, among other things, its recovery tools.[9] ICE Clear Europe has proposed to adopt a revised recovery plan to incorporate these proposed rule changes as well as make other changes (''Revised Recovery Plan'' or ''Plan''). The Revised Recovery Plan would supersede the Existing Recovery Plan.

ICE Clear Europe's Revised Recovery Plan, among other things, (a) identifies the critical services that ICE Clear Europe provides; (b) outlines recovery scenarios that may result in significant financial losses, a liquidity shortfall, suspension or failure of its critical services and related functions and systems, and damage to other financial market infrastructures; and (c) describes the recovery tools, mechanisms, and options that ICE Clear Europe may use to address a recovery scenario and continue to provide its critical services.[10] Notably, the Revised Recovery Plan is based on, and intended to be consistent with, the ICE Clear Europe Rules, Procedures, and existing risk management frameworks, policies, and procedures,[11] several aspects of which ICE Clear Europe recently revised.[12] The elements of the Revised Recovery Plan are described in further detail below.

Critical Services, Service Providers, and Interdependencies. ICE Clear Europe's prior determination that its futures and options (''F&O'') and credit default swap (''CDS'') product category clearing services, as well as its related treasury and banking services, are critical services remains in the Revised Recovery Plan. The Revised Recovery Plan identifies entities that depend on ICE Clear Europe's critical services, the service providers supporting ICE Clear Europe's critical services, and the interdependencies between ICE Clear Europe and other financial market infrastructures. ICE Clear Europe states that it mitigates risk from these relationships through various mechanisms, including, for example, by using multiple substitute providers where possible and practical. The Revised Recovery Plan further identifies technology systems that support critical services and states how risks associated with these systems are mitigated.

Recovery Scenarios, Triggers, and Early Warning Indicators. The Revised Recovery Plan analyzes two recovery scenarios. The first is default losses, where financial losses or liquidity shortfalls arise from a clearing member default or multiple clearing member defaults. The trigger for the Plan in this scenario would be when the ICE Clear Europe guaranty fund is exhausted, or is likely to exhausted, and uncovered losses remain. The second recovery scenario is non-default losses, where financial losses or liquidity shortfalls arise from investments, operational incidents, or other business activities not involving a clearing member default. The Plan would be triggered in this scenario when ICE Clear Europe's Base Capital is, or is likely to be, breached.

The Revised Recovery Plan also distinguishes between ''business as usual'' risk management (*e.g.,* margin, guaranty fund, liquid resources) and recovery scenarios, stating that recovery scenarios are where ICE Clear Europe is unable to cover losses within its business as usual risk management processes. The Revised Recovery Plan also describes the early warning indicators of a recovery trigger that ICE Clear Credit would monitor as part of its business as usual risk management.

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Exchange Act Release No. 85907 (May 21, 2019), 84 FR 24549 (May 28, 2019) (''Notice'').

[4] The term ''covered clearing agency'' is defined in Rule 17Ad–22(a)(5), 17 CFR 240.17Ad–22(a)(5).

[5] 17 CFR 240.17Ad–22(e)(3)(ii).

[6] Standards for Covered Clearing Agencies, Exchange Act Release No. 78961 (Sep. 28, 2016), 81 FR 70786, 70809 (Oct. 13, 2016) (''CCA Standards Adopting Release'').

[7] The description of the Revised Recovery Plan is substantially excerpted from the Notice. Moreover, capitalized terms not otherwise defined herein have the meanings assigned to them in ICE Clear Europe Clearing Rules (''Rules'') or the Revised Recovery Plan.

[8] Exchange Act Release No. 34–83651 (July 17, 2018), 83 FR 34891 (July 23, 2018) (SR–ICEEU–2017–016).

[9] Exchange Act Release No. 34–85848 (May 13, 2019), 84 FR 22530 (May 17, 2019) (SR–ICEEU–2019–003).

[10] In the Recovery Plan, ICE Clear Europe refers to its recovery tools, mechanisms, and options as ''Recovery Options.'' The Commission has generally referred to these items as ''recovery tools.'' *See* CCA Standards Adopting Release, 81 FR at 70810. For the purposes of this Order, the term ''recovery tools'' is used to refer to Recovery Options.

[11] Capitalized terms used but not defined herein have the meanings specified in the Rules.

[12] Exchange Act Release No. 34–86259 (July 1, 2019), 84 FR 32483 (July 8, 2019) (SR–ICEEU–2019–003).

Recovery Tools. The Revised Recovery Plan describes the key aspects of the recovery tools ICE Clear Europe may implement in a recovery scenario. Those tools include powers of assessment (Rule 909), reduced gains distribution (Rule 914), partial tear-ups (Rule 915), payment delays (Rule 110), investment loss allocation (Rule 919), invoicing back (Rule 104), and the Capital Replenishment Framework. The Revised Recovery Plan also describes the goals and procedures for designing the recovery tools, including that they are designed to be comprehensive, effective, transparent, measurable, manageable, and controllable. The Plan would specify that the recovery tools are intended to create appropriate incentives and minimize negative impact, and also would describe the governance process for development of the recovery tools that would impact Clearing Members, as well as the decision-making considerations for each recovery tool.

Decision-Making, Governance, and Communications. The Revised Recovery Plan would require that ICE Clear Europe's President (''President'') attempt to convene the Board for approval of material recovery decisions and keep regulators informed in advance of material decisions, assuming this could be done in a timely manner. If the Board could not be convened in advance of such a decision, it would be convened thereafter to ratify or modify the decision. The President would be supported by the Default Management Committees in a default loss scenario and by the Executive Risk Committee in a non-default loss scenario. Consistent with the Rules and Procedures, exercising the recovery tools would not require the approval of Clearing Members, exchanges, or any other external stakeholders, however, in making decisions regarding the use of recovery tools, the President and the Board would be required to take into consideration the interests of ICE Clear Europe, Clearing Members, customers, other stakeholders, and the broader goal of providing safe and sound central counterparty services to reduce systemic risk in an efficient and legally compliant manner.

The Revised Recovery Plan states that ICE Clear Europe's communication and coordination objectives in a recovery scenario are to provide Clearing Members, regulators, and the wider market with timely and accurate information, and to ensure effective coordination and escalation across affiliated ICE Group exchanges, clearing houses, and financial market infrastructures. ICE Clear Europe would endeavor to keep regulators informed in advance of triggering the Revised Recovery Plan or exercising recovery tools.

Recovery Playbook. The Revised Recovery Plan would include a recovery playbook for both default loss and non-default loss scenarios. ICE Clear Europe does not intend the playbook to serve as a prescriptive instruction manual for all recovery scenarios, but rather as an example and a guide for how a recovery might progress. To that end, the playbook would identify key steps in the recovery process, such as declaring a default event and determining the likely scope of losses, Board consultation, triggering the Plan, communicating with regulators, and selecting particular recovery tools.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Exchange Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to such organization.[13] For the reasons given below, the Commission finds that the proposed rule change are consistent with Section 17A(b)(3)(F) of the Exchange Act [14] and Rules 17Ad–22(e)(2), and 17Ad–22(e)(3)(ii) thereunder.[15]

A. Consistency With Section 17A(b)(3)(F) of the Exchange Act

Section 17A(b)(3)(F) of the Exchange Act requires, among other things, that the rules of ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible, and, in general, to protect investors and the public interest.[16]

As described above, the Revised Recovery Plan would identify the steps that ICE Clear Europe could take in recovery and the governance framework applicable to taking such steps. It would analyze the anticipated impact of the recovery tools, the incentives created by such tools, and the risks associated with using such tools. The Revised Recovery Plan would also explain how the tools used in the Plan are transparent, measurable, manageable, and controllable. The Commission believes that by identifying the steps ICE Clear Europe could take and the tools it would use to bring about recovery in the face of losses, the Revised Recovery Plan would increase the likelihood that recovery would be orderly, efficient, and successful. By increasing the likelihood of an orderly, efficient, and successful recovery, the Commission believes that the Revised Recovery Plan would enhance ICE Clear Europe's ability to maintain the continuity of its critical services (including its clearance of CDS transactions) during, through, and following periods of extreme stress giving rise to the need for recovery, thereby promoting the prompt and accurate settlement of CDS transactions. The Commission also believes that the Revised Recovery Plan would help assure the safeguarding of securities or funds in the custody or control of ICE Clear Europe or for which it is responsible by reducing the likelihood of a disorderly or unsuccessful recovery that could disrupt access to such securities or funds. For the same reasons, the Commission believes the Revised Recovery Plan would be consistent with the protection of investors and the public interest.

Therefore, the Commission finds that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, assure the safeguarding of securities and funds in ICE Clear Europe's custody and control, and, in general, protect investors and the public interest, consistent with the Section 17A(b)(3)(F) of the Exchange Act.[17]

B. Consistency With Rule 17Ad–22(e)(2)

Rule 17Ad–22(e)(2) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and support the public interest requirements in Section 17A of the Exchange Act applicable to clearing agencies, and the objectives of owners and participants.[18]

The Revised Recovery Plan would enhance the level of detail provided regarding the decision-making process for material recovery decisions. Specifically, the Plan states that, when possible to be done in a timely manner, the President would be required to attempt to convene the Board and obtain its approval prior to any material

[13] 15 U.S.C. 78s(b)(2)(C).

[14] 15 U.S.C. 78q–1(b)(3)(F).

[15] 17 CFR 240.17Ad–22(e)(2); (e)(3)(ii).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] 15 U.S.C. 78q–1(b)(3)(F).

[18] 17 CFR 240.17Ad–22(e)(2).

recovery decisions. In the event that the Board could not be convened in advance of such decisions, the Plan would require the President to convene the Board to ratify or modify the material recovery decision thereafter. By specifying the President's decision-making authority related to material recovery decisions and clarifying the process for the making of such material recovery decisions, the Commission believes that the Plan would enhance the overall transparency regarding material recovery decisions, which in turn would contribute to establishing, implementing, maintaining, and enforcing clear and transparent governance arrangements that support the public interest requirements in Section 17A of the Exchange Act applicable to clearing agencies, and the objectives of owners and participants.

Therefore, the Commission finds that the proposed rule change would establish clear and transport governance arrangements for the Revised Recovery Plan, consistent with Rule 17Ad–22(e)(2).[19]

C. Consistency With Rule 17Ad–22(e)(3)(ii)

Rule 17Ad–22(e)(3)(ii) requires that ICE Clear Europe establish, implement, maintain, and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by ICE Clear Europe, which includes plans for the recovery and orderly wind-down of ICE Clear Europe necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.[20]

The Commission believes that the information the Revised Recovery Plan would provide about the steps that ICE Clear Europe would take, and the tools it would use, to effectuate a recovery of ICE Clear Europe would enhance ICE Clear Europe's ability to recover from credit losses, liquidity shortfalls, general business risk losses, or other losses, consistent with Rule 17Ad–22(e)(3)(ii).[21] Specifically, by clarifying the recovery tools that ICE Clear Europe may use to effectuate a recovery, the Revised Recovery Plan would enhance ICE Clear Europe's ability to prepare in advance for, and practice the use of, such tools, which the Commission believes would enhance ICE Clear Europe's ability to use such tools effectively to carry-out a successful recovery. In addition, by continuing to utilize the Plan as the single source of information about, and steps needed to effectuate, a recovery of ICE Clear Europe, the Revised Recovery Plan continues to help ensure that ICE Clear Europe's personnel would have the information and guidance necessary to effectuate a recovery in a consistent and coordinated fashion, which could thereby increase the likelihood of a successful recovery. Moreover, the Commission believes that by identifying and assessing available recovery tools, the Revised Recovery Plan would enhance ICE Clear Europe's ability to identify in advance which tools may be most effective for different situations or needs, which in turn would enhance ICE Clear Europe's ability to use such tools effectively to bring about a recovery, consistent with Rule 17Ad–22(e)(3)(ii).[22]

Therefore, the Commission finds that the proposed rule change would be a plan for the orderly recovery of ICE Clear Europe, consistent with Rule 17Ad–22(e)(3)(ii).[23]

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act, and in particular, Section 17A(b)(3)(F) of the Exchange Act[24] and Rules 17Ad–22(e)(2), and 17Ad–22(e)(3)(ii) thereunder.[25]

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act that the proposed rule change (SR–ICEEU–2019–013) be, and hereby is, approved.[26]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15252 Filed 7–17–19; 8:45 am]

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[19] 17 CFR 240.17Ad–22(e)(2).

[20] 17 CFR 240.17Ad–22(e)(3)(ii).

[21] 17 CFR 240.17Ad–22(e)(3)(ii).

[22] 17 CFR 240.17Ad–22(e)(3)(ii).

[23] 17 CFR 240.17Ad–22(e)(3)(ii).

[24] 15 U.S.C. 78q–1(b)(3)(F).

[25] 17 CFR 240.17Ad–22(e)(2); (e)(3)(ii).

[26] In approving the proposed rule change, the Commission considered the proposal's impacts on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86362; File No. SR–NYSEArca–2019–36]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, To List and Trade Shares of JPMorgan Income Builder Blend ETF under NYSE Arca Rule 8.600–E

July 12, 2019.

I. Introduction

On May 10, 2019, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the JPMorgan Income Builder Blend ETF under NYSE Arca Rule 8.600–E. The proposed rule change was published for comment in the **Federal Register** on May 28, 2019.[3] On June 7, 2019, the Exchange filed Amendment No. 1 to the proposed rule change, and on June 21, 2019, the Exchange filed Amendment No. 2 to the proposed rule change. On July 2, 2019, the Exchange filed Amendment No. 3 to the proposed rule change, which replaced and superseded the proposed rule change, as modified by Amendment Nos. 1 and 2.[4] The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85899 (May 21, 2019), 84 FR 24563 (May 28, 2019).

[4] In Amendment No. 3, the Exchange: (1) Clarified the permitted investments of the Fund; (2) represented that the Fund's portfolio (including investments in Fixed Income Instruments (as defined below), equities, and Private ABS/MBS (as defined below)) will meet all of the generic listing requirements of Commentary .01 to NYSE Arca Rule 8.600–E applicable to the listing of Managed Fund Shares, except for those set forth in (a) Commentary .01(a)(1)(E) and .01(a)(2)(E) regarding over-the-counter (''OTC'') equity-linked notes, OTC rights, OTC warrants, and OTC CVRs; (b) Commentary .01(a)(1) regarding non-exchange-traded investment company securities; and (c) Commentary .01(b)(4) regarding Private ABS/MBS; (3) provided additional information regarding the availability of pricing information for the permitted investments of the Fund; (4) represented that the Exchange may communicate as needed regarding trading in the Shares and certain exchange-listed securities and financial instruments held by the Fund from markets and other entities with which the Exchange has in place a comprehensive surveillance sharing agreement; and (5) made other clarifications, corrections, and technical changes. Amendment No. 3 is available at: *https://www.sec.gov/comments/sr-nysearca-2019-36/srnysearca201936-5756090-186867.pdf.*

Commission has received no comments on the proposed rule change.

The Commission is publishing this notice to solicit comments on Amendment No. 3 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 3, on an accelerated basis.

II. The Exchange's Description of the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (''Shares'') of the following under NYSE Arca Rule 8.600–E, which governs the listing and trading of Managed Fund Shares [5] on the Exchange: JPMorgan Income Builder Blend ETF (the ''Fund'').[6]

The Fund is a series of J.P. Morgan Exchange-Traded Fund Trust (''Trust''), a Delaware statutory trust. J.P. Morgan Investment Management Inc. (''Adviser'' or ''Administrator'') will be the investment adviser to the Fund and also provide administrative services for and oversee the other service providers for the Fund. The Adviser is a wholly-owned subsidiary of JPMorgan Asset Management Holdings Inc., which is an indirect, wholly-owned subsidiary of JPMorgan Chase & Co., a bank holding company. JPMorgan Distribution Services, Inc. (''Distributor'') will be the distributor of the Fund's Shares.

Commentary .06 to Rule 8.600–E provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[7] In addition, Commentary .06 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund's portfolio. The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to such broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio. In the event (a) the Adviser becomes registered as a broker-dealer or newly affiliated with one or more broker-dealers, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

JPMorgan Income Builder Blend ETF

According to the Registration Statement, the Fund seeks to maximize income on a risk-adjusted basis as the primary objective, while maintaining prospects for capital appreciation as a secondary objective. The Adviser will buy and sell securities and other investments for the Fund based on the Adviser's view of strategies, sectors, and overall portfolio construction taking into account income generation, risk/return analyses, and relative value considerations.

Under normal market conditions,[8] the Fund may invest in the fixed income securities, equity securities, derivative instruments and other financial instruments described below.

The Fund may invest in the following ''Fixed Income Instruments'': [9]

- U.S. Government obligations; [10]
- U.S. Government Agency Securities (including agency asset-backed securities (''ABS'') and agency mortgage-backed securities (''MBS''); [11]
- Treasury Receipts; [12]

[5] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Rule 5.2–E(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[6] The Trust is registered under the 1940 Act. On July 31, 2018, the Trust filed with the Commission an amendment to its registration statement on Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a) (''Securities Act'') and the 1940 Act relating to the Fund (File Nos. 333–191837 and 811–22903) (the ''Registration Statement''). The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement. The Trust will file an amendment to the Registration Statement as necessary to conform to representations in this filing. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 31990 (February 9, 2016) (''Exemptive Order''). Investments made by the Fund will comply with the conditions set forth in the Exemptive Order.

[7] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[8] The term ''normal market conditions'' is defined in NYSE Arca Rule 8.600–E(c)(5).

[9] Other than ''Private ABS/MBS, which will not meet the criteria of Commentary .01(b)(4) to NYSE Arca Rule 8.600–E, as discussed below, all Fixed Income Instruments would meet the generic criteria of Rule 8.600–E, Comm. .01(b).

[10] Examples of U.S. Government obligations include direct obligations of the U.S. Treasury, including Treasury bills, notes and bonds, all of which are backed as to principal and interest payments by the full faith and credit of the United States, and separately traded principal and interest component parts of such obligations that are transferable through the Federal book-entry system known as Separate Trading of Registered Interest and Principal of Securities (''STRIPS'') and Coupons Under Book Entry Safekeeping (''CUBES'').

[11] Examples of U.S. Government Agency Securities include securities issued or guaranteed by agencies and instrumentalities of the U.S. government. These include all types of securities issued by the Government National Mortgage Association (''Ginnie Mae''), the Federal National Mortgage Association (''Fannie Mae'') and the Federal Home Loan Mortgage Corporation (''Freddie Mac''), including funding notes, subordinated benchmark notes, collateralized mortgage obligations (''CMOs'') and Real Estate Mortgage Investment Conduits (''REMICs'').

[12] Treasury Receipts are interests in separately traded interest and principal component parts of U.S. Treasury obligations that are issued by banks or brokerage firms and that are created by depositing U.S. Treasury notes and U.S. Treasury bonds into a special account at a custodian bank. Receipts include Treasury Receipts (''TRs''), Treasury Investment Growth Receipts (''TIGRs''),

- Trust preferred securities;
- Zero-coupon, pay-in-kind and deferred payment securities; [13]
- Variable and floating rate instruments;
- Inverse floating rate securities;
- Synthetic variable rate instruments; [14]
- Municipal securities (other than auction rate municipal securities);
- Auction rate municipal securities and auction rate preferred securities;
- Brady bonds;
- Non-agency ABS; [15]
- Non-agency MBS; [16]
- Stripped MBS; [17]
- Custodial receipts; [18]
- Inflation-linked securities, including Treasury Inflation Protected Securities (''TIPS'');
- Loan assignments and participations, and commitments to purchase loan assignments;
- Adjustable rate mortgage loans (''ARMs'');
- Mortgages (directly held); [19]
- Mortgage dollar rolls;
- Short-term funding agreements; [20]
- Sovereign obligations and obligations of supranational agencies;
- Corporate debt securities of U.S. and foreign issuers; and
- Convertible securities.

The Fund may hold cash and cash equivalents.[21]

The Fund may purchase and sell securities on a when-issued, delayed delivery, or forward commitment basis.

The Fund may invest in private placements, restricted securities and Rule 144A securities.

The Fund may invest in the following exchange-listed equity securities: U.S. and foreign exchange-listed common stocks of U.S. and foreign corporations, U.S. and foreign exchange-listed preferred stocks of U.S. and foreign corporations, U.S. and foreign exchange-listed warrants of U.S. and foreign corporations, U.S. and foreign exchange-listed rights of U.S. and foreign corporations, U.S. and foreign exchange-listed master limited partnerships (''MLPs''), U.S. and foreign exchange-listed real estate investment trusts (''REITs''), U.S. and foreign exchange-listed convertible securities.

The Fund may invest in U.S. and foreign exchange-listed and non-exchange-traded Depositary Receipts.[22]

The Fund may hold exchange-traded funds (''ETFs''),[23] and U.S. exchange-traded closed-end funds.

The Fund may invest in securities of non-exchange-traded investment company securities, subject to applicable limitations under Section 12(d)(1) of the 1940 Act.

The Fund may hold over-the-counter (''OTC'') equity-related structured investments.[24]

The Fund may hold the following U.S. and foreign exchange-listed and OTC derivative instruments: OTC foreign currency forwards; U.S. and foreign exchange-listed futures and options on stocks, Fixed Income Instruments, interest rates, credit, currencies, commodities or related indices; and OTC options on stocks, Fixed Income Instruments, interest rates, credit, currencies, commodities or related indices.

The Fund may invest in exchange-traded or OTC total return swaps on U.S. and foreign equities, U.S. and foreign equity indices, currencies, interest rates, inflation, commodities, Fixed Income Instruments and Fixed Income Instruments indexes.

The Fund may engage in foreign currency transactions which involve strategies used to hedge against currency risks, for other risk management purposes or to increase income or gain to the Fund. These strategies may consist of use of any of the following: Options on currencies, currency futures, options on such futures, forward foreign currency transactions (including non-deliverable forwards (''NDFs'')), forward rate agreements, spot currency transactions, and currency swaps, caps and floors.

The Fund may hold exchange-traded or non-exchange-traded contingent value rights (''CVRs'').[25]

and Certificates of Accrual on Treasury Securities (''CATS'').

[13] Zero-coupon securities are securities that are sold at a discount to par value and on which interest payments are not made during the life of the security. Pay-in-kind securities are securities that have interest payable by delivery of additional securities. Deferred payment securities are zero-coupon debt securities which convert on a specified date to interest bearing debt securities.

[14] Synthetic variable rate instruments are instruments that generally involve the deposit of a long-term tax exempt bond in a custody or trust arrangement and the creation of a mechanism to adjust the long-term interest rate on the bond to a variable short-term rate and a right (subject to certain conditions) on the part of the purchaser to tender it periodically to a third party at par.

[15] For purposes of this filing, non-agency ABS are collateralized bond obligations (''CBOs''), collateralized loan obligations (''CLOs''), and other collateralized debt obligations (''CDOs'').

[16] For purposes of this filing, non-agency MBS are collateralized mortgage obligations (''CMOs''); commercial mortgage-backed securities (''CMBS''); residential mortgage-backed securities (''RMBS''); and principal-only (PO) and interest-only (IO) stripped MBS. Non-agency ABS and non-agency MBS are referred to herein as ''Private ABS/MBS.''

[17] Stripped MBS are derivative multi-class mortgage securities which are usually structured with two classes of shares that receive different proportions of the interest and principal from a pool of mortgage assets. These include IO and PO securities issued outside a Real Estate Mortgage Investment Conduit (''REMIC'') or CMO structure.

[18] The Fund may acquire securities in the form of custodial receipts that evidence ownership of future interest payments, principal payments or both on certain U.S. Treasury notes or bonds in connection with programs sponsored by banks and brokerage firms.

[19] Directly held mortgages are debt instruments secured by real property.

[20] Short-term funding agreements are agreements issued by banks and highly rated U.S. insurance companies such as Guaranteed Investment Contracts (''GICs'') and Bank Investment Contracts (''BICs'').

[21] For purposes of this filing, cash equivalents include the securities included in Commentary .01(c) to NYSE Arca Rule 8.600–E.

[22] Depositary Receipts include American Depositary Receipts (''ADRs''), Global Depositary Receipts (''GDRs'') and European Depositary Receipts (''EDRs''). ADRs are receipts typically issued by an American bank or trust company that evidence ownership of underlying securities issued by a foreign corporation. EDRs are receipts issued by a European bank or trust company evidencing ownership of securities issued by a foreign corporation. GDRs are receipts issued throughout the world that evidence a similar arrangement. ADRs, EDRs and GDRs may trade in foreign currencies that differ from the currency the underlying security for each ADR, EDR or GDR principally trades in. Generally, ADRs, in registered form, are designed for use in the U.S. securities markets. EDRs, in registered form, are used to access European markets. GDRs, in registered form, are tradable both in the United States and in Europe and are designed for use throughout the world. No more than 10% of the equity weight of the Fund's portfolio will be invested in non-exchange-traded ADRs.

[23] For purposes of this filing, ''ETFs'' are Investment Company Units (as described in NYSE Arca Rule 5.2–E(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Rule 8.100–E); and Managed Fund Shares (as described in NYSE Arca Rule 8.600–E). All ETFs will be listed and traded in the U.S. on a national securities exchange. While the Fund may invest in inverse ETFs, the Fund will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs.

[24] An equity-related structured investment is a security having a return tied to an underlying index or other security or asset class. Equity-related structured investments generally are individually negotiated agreements and may be traded OTC. Structured investments are organized and operated to restructure the investment characteristics of the underlying index, currency, commodity or financial instrument. OTC equity-related structured investments are OTC rights, OTC warrants and OTC equity-linked notes. As discussed below, OTC equity-related structured investments will not meet generic criteria of 8.600–E, Comm. .01(a).

[25] For purposes of this filing, CVRs are rights provided to shareholders of a company in connection with a corporate restructuring or acquisition. These rights relate to additional benefits to shareholders if a certain event occurs. CVRs frequently have an expiration date relating to the times that contingent events must occur. CVRs related to a company's stock are generally related to the price performance of such stock. The Adviser represents that the Fund will not actively invest in such securities but may, at times, receive a distribution of such securities in connection with the Fund's holdings in other securities. Therefore, the Fund's holdings in non-exchange-traded CVRs, if any, would not be utilized to further the Fund's investment objective and would not be acquired as the result of the Fund's voluntary investment decisions.

The Fund may engage in short sales of any financial instruments in which it may invest.

The Fund will not invest in securities or other financial instruments that have not been described in this proposed rule change.

Other Restrictions

The Fund may invest up to 20% of the Fund's assets in non-exchange-traded investment company securities.

The Fund may invest up to 15% of the Fund's assets in the aggregate in OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs.

The Fund's investments, including derivatives, will be consistent with the Fund's investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).[26]

The Fund's Use of Derivatives

Investments in derivative instruments will be made in accordance with the Fund's investment objective and policies.

To limit the potential risk associated with such transactions, the Fund will enter into offsetting transactions or segregate or ''earmark'' assets determined to be liquid by the Adviser in accordance with procedures established by the Trust's Board of Trustees (the ''Board''). In addition, the Fund has included appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of the Fund, including the Fund's use of derivatives, may give rise to leverage, causing the Fund to be more volatile than if it had not been leveraged.

Creation and Redemption of Shares

The consideration for a purchase of Creation Units will generally be cash, but may consist of an in-kind deposit of a designated portfolio of equity securities and other investments (the ''Deposit Instruments'') and an amount of cash computed as described below (the ''Cash Amount'') under some circumstances. The Cash Amount together with the Deposit Instruments, as applicable, are referred to as the ''Portfolio Deposit,'' which represents the minimum initial and subsequent investment amount for a Creation Unit of the Fund. The size of a Creation Unit will be 50,000 Shares and will be subject to change.

In the event the Fund requires Deposit Instruments and a Cash Amount in consideration for purchasing a Creation Unit, the function of the Cash Amount is to compensate for any differences between the net asset value (''NAV'') per Creation Unit and the Deposit Amount (as defined below). The Cash Amount would be an amount equal to the difference between the NAV of the Shares (per Creation Unit) and the ''Deposit Amount,'' which is an amount equal to the aggregate market value of the Deposit Instruments. If the Cash Amount is a positive number (the NAV per Creation Unit exceeds the Deposit Amount), the Authorized Participant will deliver the Cash Amount. If the Cash Amount is a negative number (the NAV per Creation Unit is less than the Deposit Amount), the Authorized Participant will receive the Cash Amount. The Administrator, through the National Securities Clearing Corporation (''NSCC''), will make available on each business day, immediately prior to the opening of business on the Exchange (currently 9:30 a.m. Eastern time (''E.T.'')), the list of the names and the required number of shares of each Deposit Instrument to be included in the current Portfolio Deposit (based on information at the end of the previous business day), as well as information regarding the Cash Amount for the Fund.

The identity and number of the Deposit Instruments and Cash Amount required for the Portfolio Deposit for the Fund changes as rebalancing adjustments and corporate action events are reflected from time to time by the Adviser with a view to the investment objective of the Fund. In addition, the Trust reserves the right to accept a basket of securities or cash that differs from Deposit Instruments or to permit the substitution of an amount of cash (*i.e.,* a ''cash in lieu'' amount) to be added to the Cash Amount to replace any Deposit Instrument which may, among other reasons, not be available in sufficient quantity for delivery, not be permitted to be re-registered in the name of the Trust as a result of an in-kind creation order pursuant to local law or market convention or for other reasons as described in the Registration Statement, or which may not be eligible for trading by a Participating Party (defined below).

Procedures for Creation of Creation Units

To be eligible to place orders with the Distributor to create Creation Units of the Fund, an entity or person either must be (1) a ''Participating Party,'' *i.e.,* a broker-dealer or other participant in the clearing process through the Continuous Net Settlement System of the NSCC; or (2) a Depositary Trust Company (''DTC'') Participant, which, in either case, must have executed an agreement with the Distributor (''Participant Agreement''). Such Participating Party and DTC Participant are collectively referred to as an ''Authorized Participant.'' All orders to create Creation Units must be received by the Distributor no later than the closing time of the regular trading session on the Exchange (''Closing Time'') (ordinarily 4:00 p.m. E.T.), in each case on the date such order is placed in order for creation of Creation Units to be effected based on the NAV of the Fund as determined on such date.

Redemption of Creation Units

Shares may be redeemed only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Distributor, only on a business day and only through a Participating Party or DTC Participant who has executed a Participant Agreement. All orders to redeem Creation Units must be received by the Distributor no later than the Exchange Closing Time (ordinarily 4:00 p.m. E.T.).

Although the Fund will generally pay redemption proceeds in cash, there may be instances when it will make redemptions in-kind.[27] In these instances, the Administrator, through NSCC, makes available immediately prior to the opening of business on the Exchange (currently 9:30 a.m. E.T.) on each day that the Exchange is open for business, the identity of the Fund's assets and/or an amount of cash that will be applicable (subject to possible amendment or correction) to redemption requests received in proper form on that day. With respect to redemptions in-kind, the redemption proceeds for a Creation Unit generally consist of ''Redemption Instruments'' (which are securities received on redemption) as announced by the Administrator on the business day of the request for redemption, plus cash in an amount equal to the difference between the NAV of the Shares being

[26] The Fund's broad-based securities benchmark index will be identified in a future amendment to the Registration Statement following the Fund's first full calendar year of performance.

[27] The Adviser represents that, to the extent the Trust effects the creation or redemption of Shares in cash, such transactions will be effected in the same manner for all Authorized Participants.

redeemed, as next determined after a receipt of a request in proper form, and the value of the Redemption Instruments.

Disclosed Portfolio

The Fund's disclosure of derivative positions in the applicable Disclosed Portfolio includes information that market participants can use to value these positions intraday. On a daily basis, the Fund will disclose the information regarding the Disclosed Portfolio required under NYSE Arca Rule 8.600–E(c)(2) to the extent applicable. The Fund's website information will be publicly available at no charge.

Impact on Arbitrage Mechanism

The Adviser believes there will be minimal impact to the arbitrage mechanism as a result of the use of derivatives. Market makers and participants should be able to value derivatives as long as the positions are disclosed with relevant information. The Adviser believes that the price at which Shares trade will continue to be disciplined by arbitrage opportunities created by the ability to purchase or redeem Shares at their NAV, which should ensure that Shares will not trade at a material discount or premium in relation to their NAV.

The Adviser does not believe there will be any significant impacts to the settlement or operational aspects of the Fund's arbitrage mechanism due to the use of derivatives. Because derivatives generally are not eligible for in-kind transfer, they will typically be substituted with a ''cash in lieu'' amount when the Fund processes purchases or redemptions of creation units in-kind.

Application of Generic Listing Requirements

The Exchange is submitting this proposed rule change because the portfolio for the Fund will not meet all of the ''generic'' listing requirements of Commentary .01 to NYSE Arca Rule 8.600–E applicable to the listing of Managed Fund Shares. The Fund's portfolio would meet all such requirements except for those set forth in NYSE Arca Rule 8.600–E, Commentary .01(a)(1)(E) and .01(a)(2)(E) regarding OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs; Commentary .01(a)(1) regarding non-exchange-traded investment company securities; and Commentary .01(b)(4)[28] regarding Private ABS/MBS.

With respect to Commentary .01(a)(1)(E) and .01(a)(2)(E) to NYSE Arca Rule 8.600–E, as noted above, the Fund may hold OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs, which are deemed non-exchange-traded equity securities for purposes of this filing.[29] Because such securities are not listed on a national securities exchange or an exchange that has last-sale reporting, such securities would not meet the criteria of Commentary .01(a)(1)(E) and (a)(2)(E) to NYSE Arca Rule 8.600–E applicable to U.S. Component Stocks and Non-U.S. Component Stocks. As noted above, the Fund may invest up to 15% of the Fund's assets in the aggregate in OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs. The Exchange believes that this limitation is appropriate in that OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs are providing debt or equity-oriented exposures or are received in connection with the Fund's previous investment in fixed income securities or equities. With respect to OTC CVRs, the Adviser represents that the Fund will not actively invest in such securities but may, at times, receive a distribution of such securities in connection with the Fund's holdings in other securities. Therefore, the Fund's holdings in OTC CVRs, if any, would not be utilized to further the Fund's investment objective and would not be acquired as the result of the Fund's voluntary investment decisions.[30] All of the other equity securities held by the Fund (with the exception of non-exchange-traded investment company securities, as discussed below) will comply with the generic requirements Commentary .01(a)(1) and (a)(2) to NYSE Arca Rule 8.600–E.

The Fund may invest in non-exchange-traded investment company securities, which are equity securities. Because such securities must satisfy applicable 1940 Act diversification requirements, and have a net asset value based on the value of securities and financial assets the investment company holds, it is both unnecessary and inappropriate to apply to such investment company securities the criteria in Commentary .01(a)(1). As noted above, the Fund may invest up to 20% of the Fund's assets in non-exchange-traded investment company securities. The Fund's investment in shares of non-exchange-traded open-end management investment company securities will be utilized in order to obtain income on short-term cash balances while awaiting attractive investment opportunities, to provide liquidity in preparation for anticipated redemptions or for defensive purposes, which will allow the Fund to obtain the benefits of a more diversified portfolio available in the shares of non-exchange-traded open-end management investment company securities than might otherwise be available. Moreover, such investments, which may include mutual funds that invest, for example, principally in fixed income securities, would be utilized to help the Fund meet its investment objective and to equitize cash in the short term. The Fund will invest in such securities only to the extent that those investments would be consistent with the requirements of Section 12(d)(1) of the 1940 Act and the rules thereunder.

The Exchange notes that Commentary .01(a)(1)(A) through (D) to Rule 8.600–E exclude application of those provisions to certain ''Derivative Securities Products'' that are exchange-traded investment company securities, including Investment Company Units (as described in NYSE Arca Rule 5.2–E(j)(3)), Portfolio Depositary Receipts (as

[28] Commentary .01(b)(4) provides that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio must be either: (a) From issuers that are required to file reports pursuant to Sections 13 and 15(d) of the Act; (b) from issuers that have a worldwide market value of its outstanding common equity held by non-affiliates of $700 million or more; (c) from issuers that have outstanding securities that are notes, bonds debentures, or evidence of indebtedness having a total remaining principal amount of at least $1 billion; (d) exempted securities as defined in Section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country.

[29] Commentary .01(a) to NYSE Arca Rule 8.600–E provides criteria applicable to exchange-traded equity securities held by a series of Managed Fund Shares. Among such criteria, equity securities that are U.S. Component Stocks as described in NYSE Arca Rule 5–2–E(j)(3) shall be listed on a national securities exchange and shall be NMS Stocks as defined in Rule 600 of Regulation NMS under the Act (with a limited exception for certain ADRs). Equity securities that are Non-U.S. Component Stocks as described in NYSE Arca Rule 5–2–E(j)(3) shall be listed and traded on an exchange that has last-sale reporting.

[30] The Commission has previously approved listing and trading of series of Managed Fund Shares that hold OTC equity securities such as common stocks, rights, warrants and CVRs. See, *e.g.,* Securities Exchange Act Release Nos. 77904 (May 25, 2016) (SR–NYSEArca–2016–17) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, to List and Trade of Shares of the JPMorgan Diversified Alternative ETF under NYSE Arca Equities Rule 8.600); 79683 (December 23, 2016) (SR–NYSEArca–2016–82) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3 Thereto, to List and Trade Shares of the JPMorgan Diversified Event Driven ETF under NYSE Arca Equities Rule 8.600 82492 (January 12, 2018) (SR–NYSEArca–2017–87) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 6, to List and Trade Shares of the JPMorgan Long/Short ETF under NYSE Arca Rule 8.600–E).

described in NYSE Arca Rule 8.100–E) and Managed Fund Shares (as described in NYSE Arca Rule 8.600–E).[31] In its 2008 Approval Order approving amendments to Commentary .01(a) to Rule 5.2(j)(3) that exclude Derivative Securities Products from certain provisions of Commentary .01(a) (which exclusions are similar to those in Commentary .01(a)(1) to Rule 8.600–E), the Commission stated that ''based on the trading characteristics of Derivative Securities Products, it may be difficult for component Derivative Securities Products to satisfy certain quantitative index criteria, such as the minimum market value and trading volume limitations.'' The Exchange notes that it would be difficult or impossible to apply to non-exchange-traded investment company securities the generic quantitative criteria (*e.g.,* market capitalization, trading volume, or portfolio criteria) in Commentary .01(a) through (d) applicable to U.S. Component Stocks. For example, the requirement for U.S. Component Stocks in Commentary .01(a)(1)(B) that there be minimum monthly trading volume of 250,000 shares, or minimum notional volume traded per month of $25,000,000, averaged over the last six months is tailored to exchange-traded securities (*e.g.,* U.S. Component Stocks) and not to mutual fund shares, which do not trade in the secondary market. Moreover, application of such criteria would not serve its purpose with respect to U.S. Component Stocks, namely, to establish minimum liquidity and diversification criteria for U.S. Component Stocks held by series of Managed Fund Shares.

The Exchange notes that the Commission has previously approved listing and trading of an issue of Managed Fund Shares that may invest in equity securities that are non-exchange-traded securities of other open-end investment company securities notwithstanding that the fund would not meet the requirements of Commentary .01(a)(1)(A) through (E) to Rule 8.600–E with respect to such fund's investments in such securities.[32] Thus, the Exchange believes that it is appropriate to permit the Fund to invest in non-exchange-traded open-end management investment company securities, as described above.

The Fund will not comply with the requirements in Commentary .01(b)(4) to Rule 8.600–E that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria specified in Commentary .01(b)(4), because certain Private ABS/MBS by their nature cannot satisfy the criteria in Commentary .01(b)(4).[33] Instead, the Exchange proposes that the Fund's investments in Fixed Income Instruments other than Private ABS/MBS will be required to comply with the requirements of Commentary .01(b)(4).[34] The Exchange believes that excluding Private ABS/MBS from the 90% calculation in Commentary .01(b)(4) is consistent with the Act because the Fund's portfolio will minimize the risk to the overall Fund associated with any particular holding of the Fund as a result of the diversification provided by the investments and the Adviser's selection process, which closely monitors investments to ensure maintenance of credit and liquidity standards. Further, the Exchange believes that this alternative limitation is appropriate because Commentary .01(b)(4) to Rule 8.600–E is not designed for structured finance vehicles such as Private ABS/MBS.[35]

The Exchange notes that the Commission has previously approved the listing of Managed Fund Shares with similar investment objectives and strategies without imposing requirements that a certain percentage of such funds' securities meet one of the criteria set forth in Commentary .01(b)(4).[36]

Deviations from the generic requirements are necessary for the Fund to achieve its investment objective in a manner that is cost-effective and that maximizes investors' returns. Further, the proposed alternative requirements are narrowly tailored to allow the Fund to achieve its investment objective in manner that is consistent with the principles of Section 6(b)(5) of the Act. As a result, it is in the public interest to approve listing and trading of Shares of the Fund on the Exchange pursuant to the requirements set forth herein.

The Exchange notes that, other than NYSE Arca Rule 8.600–E, Commentary .01(a)(1)(E) and .01(a)(2)(E) regarding OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs; Commentary .01(a)(1) regarding non-exchange-traded investment company securities; and Commentary .01(b)(4)

[31] The Commission initially approved the Exchange's proposed rule change to exclude ''Derivative Securities Products'' (*i.e.,* Investment Company Units and securities described in Section 2 of Rule 8) and ''Index-Linked Securities (as described in Rule 5.2–E(j)(6)) from Commentary .01(a)(A)(1) through (4) to Rule 5.2–E(j)(3 in Securities Exchange Act Release No. 57751 (May 1, 2008), 73 FR 25818 (May 7, 2008) (SR–NYSEArca–2008–29) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to Amend the Eligibility Criteria for Components of an Index Underlying Investment Company Units) (''2008 Approval Order''). *See also,* Securities Exchange Act Release No. 57561 (March 26, 2008), 73 FR 17390 (April 1, 2008) (Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto to Amend the Eligibility Criteria for Components of an Index Underlying Investment Company Units). The Commission subsequently approved generic criteria applicable to listing and trading of Managed Fund Shares, including exclusions for Derivative Securities Products and Index-Linked Securities in Commentary .01(a)(1)(A) through (D), in Securities Exchange Act Release No. 78397 (July 22, 2016), 81 FR 49320 (July 27, 2016) (Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 7 Thereto, Amending NYSE Arca Equities Rule 8.600 To Adopt Generic Listing Standards for Managed Fund Shares). *See also,* Amendment No. 7 to SR–NYSEArca–2015–110, available at *https://www.sec.gov/comments/sr-nysearca-2015-110/nysearca2015110-9.pdf.*

[32] *See* Securities Exchange Act Release No. 83319 (May 24, 2018), 83 FR 25097 (May 31, 2018) (SR–NYSEArca–2018–15) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to Continue Listing and Trading Shares of the PGIM Ultra Short Bond ETF Under NYSE Arca Rule 8.600–E).

[33] Private ABS/MBS are generally issued by special purpose vehicles, so the criteria in Commentary .01(b)(4) to Rule 8.600–E regarding an issuer's market capitalization and the remaining principal amount of an issuer's securities are typically unavailable with respect to Private ABS/MBS, even though such Private ABS/MBS may own significant assets.

[34] Private ABS/MBS will comply with Commentary .01(b)(5), which provides that non-agency, non-government-sponsored entity (''GSE'') and privately-issued mortgage-related and other asset-backed securities components of a portfolio shall not account, in the aggregate, for more than 20% of the weight of the portfolio.

[35] The Commission has previously approved listing on a national securities exchange of a series of Managed Fund Shares that principally holds fixed income securities and whose holdings of securities similar to Private ABS/MBS (as described herein) do not comply with criteria comparable to those included in Commentary .01(b)(4) to Rule 8.600–E. *See* Securities Exchange Act Release No 85701 (April 22, 2019), 84 FR 17902 (April 26, 2019) (SR–CboeBZX–2019–016) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Allow the JPMorgan Core Plus Bond ETF to Hold Certain Instruments in a Manner that May Not Comply with Rule 14.11(i), Managed Fund Shares).

[36] *See, e.g.,* Exchange Act Release Nos. 67894 (September 20, 2012) 77 FR 59227 (September 26, 2012) (SR–BATS–2012–033) (order approving the listing and trading of shares of the iShares Short Maturity Bond Fund); 70342 (September 6, 2013), 78 FR 56256 (September 12, 2013) (SR–NYSEArca–2013–71) (order approving the listing and trading of shares of the SPDR SSgA Ultra Short Term Bond ETF, SPDR SSgA Conservative Ultra Short Term Bond ETF and SPDR SSgA Aggressive Ultra Short Term Bond ETF). *See also,* Securities Exchange Act Release Nos. 84047 (September 6, 2018), 83 FR 46200 (September 12, 2018) (SR–NASDAQ–2017–128) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, to List and Trade Shares of the Western Asset Total Return ETF); 85022 (January 31, 2019), 25 FR 2265 (February 6, 2019) (SR–NASDAQ–2018–080) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 2 and 3, To List and Trade Shares of the BrandywineGLOBAL—Global Total Return ETF).

regarding Private ABS/MBS, as described above, the Fund's portfolio will meet all other requirements of Rule 8.600–E, including the generic listing requirements in Commentary .01 to Rule 8.600–E.

Availability of Information

The Fund's website (*www.jpmorganfunds.com*), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Fund's website will include additional quantitative information updated on a daily basis, including, for the Fund, (1) daily trading volume, the prior business day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''),[37] and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Adviser will disclose on the Fund's website the Disclosed Portfolio for the Fund as defined in NYSE Arca Rule 8.600–E(c)(2) that will form the basis for the Fund's calculation of NAV at the end of the business day.[38]

Investors can also obtain the Trust's Statement of Additional Information (''SAI''), the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov*.

Quotation and last sale information for the Shares and for portfolio holdings of the Fund that are U.S. exchange-listed, including common stocks, preferred stocks, warrants, rights, MLPs, REITs, convertible securities, ETFs, closed-end funds, and U.S. exchange-listed Depositary Receipts will be available via the CTA high speed line. Price information for the following U.S. and foreign exchange-traded securities and financial instruments will be available from the exchange on which they are listed: Futures; options on futures; options other than options on futures; swaps; CVRs, foreign exchange-traded Depositary Receipts and equity-linked notes. Quotation and last sale information for exchange-listed options cleared via the Options Clearing Corporation will be available via the Options Price Reporting Authority. Quotation and last sale information for foreign exchange-listed equity securities will be available from the exchanges on which they trade and from major market data vendors, as applicable. Information regarding market price and trading volume for the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

Quotation information for OTC options, cash equivalents, swaps, and Fixed Income Instruments may be obtained from brokers and dealers who make markets in such securities or through nationally recognized pricing services through subscription agreements. Forwards and spot currency price information will be available from major market data vendors. Price information for non-exchange-traded investment company securities, OTC equity-linked notes, OTC warrants, OTC rights, OTC CVRs, OTC Depositary Receipts, 144A securities, private placement securities and restricted securities is available from major market data vendors. Price information for certain municipal securities held by the Fund is available through Electronic Municipal Market Access (''EMMA'') of the Municipal Securities Rulemaking Board (''MSRB'').

In addition, the PIV, as defined in NYSE Arca Rule 8.600–E(c)(3), will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session.[39] The dissemination of the PIV, together with the Disclosed Portfolio, will allow investors to determine the approximate value of the underlying portfolio of the Fund on a daily basis and will provide a close estimate of that value throughout the trading day.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.[40] Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares of the Fund inadvisable.

Trading in the Shares will be subject to NYSE Arca Rule 8.600–E(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m. E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Except as described herein, the Shares of the Fund will conform to the initial and continued listing criteria under NYSE Arca Rule 8.600–E. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A–3[41] under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares of the Fund that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances

[37] The Bid/Ask Price of the Fund's Shares will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

[38] Under accounting procedures to be followed by the Fund, trades made on the prior business day (''T'') will be booked and reflected in NAV on the current business day (''T+1''). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[39] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available PIVs taken from the CTA or other data feeds.

[40] *See* NYSE Arca Rule 7.12–E.

[41] 17 CFR 240 10A–3.

administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[42] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, certain exchange-listed equity securities, certain futures, and certain exchange-traded options with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities and financial instruments from such markets and other entities. In addition, the Exchange may obtain information and communicate as needed regarding trading in such securities and financial instruments from markets and other entities with which the Exchange has in place a comprehensive surveillance sharing agreement.[43] FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's Trade Reporting and Compliance Engine (''TRACE'').

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio holdings or reference asset, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares of the Fund. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) NYSE Arca 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Early and Late Trading Sessions when an updated PIV will not be calculated or publicly disseminated; (4) how information regarding the PIV and the Disclosed Portfolio is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares of the Fund will be calculated after 4:00 p.m. E.T. each trading day.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[44] that an exchange have rules that are 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, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.600–E. The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to such broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio. The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, certain exchange-listed equity securities, certain futures, and certain exchange-traded options with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities and financial instruments from such markets and other entities. In addition, the Exchange may obtain information regarding trading in such securities and financial instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.

The PIV, as defined in NYSE Arca Rule 8.600–E (c)(3), will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session. The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), deemed illiquid

[42] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[43] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[44] 15 U.S.C. 78f(b)(5).

by the Adviser, consistent with Commission guidance.

Except as described herein, the Shares of the Fund will conform to the initial and continued listing criteria under NYSE Arca Rule 8.600–E. The Exchange represents that, for initial and/or continued listing, the Fund will be in compliance with Rule 10A–3 under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares of the Fund that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. The Fund's portfolio holdings will be disclosed on its website daily after the close of trading on the Exchange and prior to the opening of trading on the Exchange the following day. On a daily basis, the Fund will disclose the information regarding the Disclosed Portfolio required under NYSE Arca Rule 8.600–E (c)(2) to the extent applicable. The Fund's website information will be publicly available at no charge.

Investors can also obtain the Trust's SAI, the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov*.

The website for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Moreover, prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares of the Fund. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to NYSE Arca Rule 8.600–E(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the PIV, the Disclosed Portfolio, and quotation and last sale information for the Shares. The Fund's investments, including derivatives, will be consistent with the Fund's investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).

With respect to the Fund's investment in Private ABS/MBS, the proposed non-compliance with the requirements in Commentary .01(b)(4) to Rule 8.600–E that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria specified in Commentary .01(b)(4) is appropriate because certain Private ABS/MBS by their nature cannot satisfy the criteria in Commentary .01(b)(4). Instead, the Exchange proposes that the Fund's investments in Fixed Income Instruments other than Private ABS/MBS will be required to comply with the requirements of Commentary .01(b)(4), and Private ABS/MBS will be limited to 20% of the Fund's portfolio. The Exchange believes that excluding Private ABS/MBS from the 90% calculation in Commentary .01(b)(4) is consistent with the Act because the Fund's portfolio will minimize the risk to the overall Fund associated with any particular holding of the Fund as a result of the diversification provided by the investments and the Adviser's selection process, which closely monitors investments to ensure maintenance of credit and liquidity standards. Further, the Exchange believes that this alternative limitation is appropriate because Commentary .01(b)(4) to Rule 8.600–E is not designed for structured finance vehicles such as Private ABS/MBS.

The Exchange notes that the Commission has previously approved the listing of Managed Fund Shares with similar investment objectives and strategies without imposing requirements that a certain percentage of such funds' securities meet one of the criteria set forth in Commentary .01(b)(4).[45]

The Fund may invest in shares of non-exchange-traded open-end management investment company securities, which are equity securities. Therefore, the Fund will not comply with the requirements of Commentary .01(a)(1) to NYSE Arca Rule 8.600–E (U.S. Component Stocks) with respect to its holdings in such equity securities. It is appropriate and in the public interest to approve listing and trading of Shares of the Fund notwithstanding that the Fund's holdings in such securities would not meet the requirements of Commentary .01(a)(1)(A) through (E) to Rule 8.600–E. The Fund's investment in non-exchange-traded open-end management investment company securities will not exceed 20% of the Fund's assets. The Fund's investment in shares of non-exchange-traded open-end management investment company securities will be utilized in order to obtain income on short-term cash balances while awaiting attractive investment opportunities, to provide liquidity in preparation for anticipated redemptions or for defensive purposes, which will allow the Fund to obtain the benefits of a more diversified portfolio available in the shares of non-exchange-traded open-end management investment company securities than might otherwise be available. Moreover, such investments, which may include mutual funds that invest, for example, principally in fixed income securities, would be utilized to help the Fund meet its investment objective and to equitize cash in the short term. The Fund will invest in such securities only to the extent that those investments would be consistent with the requirements of Section 12(d)(1) of the 1940 Act and the rules thereunder. Because such securities must satisfy applicable 1940 Act diversification requirements, and have a net asset value based on the value of securities and financial assets the investment company holds, it is both unnecessary and inappropriate to apply to such investment company securities the criteria in Commentary .01(a)(1).

The Exchange notes that it would be difficult or impossible to apply to mutual fund shares certain of the generic quantitative criteria (*e.g.,* market capitalization, trading volume, or portfolio criteria) in Commentary .01 (A) through (D) applicable to U.S. Component Stocks. For example, the requirements for U.S. Component Stocks in Commentary .01(a)(1)(B) that there be minimum monthly trading volume of 250,000 shares, or minimum notional volume traded per month of $25,000,000, averaged over the last six months are tailored to exchange-traded securities (*i.e.,* U.S. Component Stocks) and not to mutual fund shares, which do not trade in the secondary market

[45] *See* note 37 [sic], *supra.*

and for which no such volume information is reported. In addition, Commentary .01(a)(1)(A) relating to minimum market value of portfolio component stocks, Commentary .01(a)(1)(C) relating to weighting of portfolio component stocks, and Commentary .01(a)(1)(D) relating to minimum number of portfolio components are not appropriately applied to open-end management investment company securities; open-end investment companies hold multiple individual securities as disclosed publicly in accordance with the 1940 Act, and application of Commentary .01(a)(1)(A) through (D) would not serve the purposes served with respect to U.S. Component Stocks, namely, to establish minimum liquidity and diversification criteria for U.S. Component Stocks held by series of Managed Fund Shares.

To the extent the Fund invests in OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs, the Fund will not comply with the requirements of Commentary .01(a)(1)(E) and .01(a)(2)(E. with respect to its holdings in such equity securities. As noted above, the Fund may invest up to 15% of the Fund's assets in the aggregate in OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs. The Exchange believes that this limitation is appropriate in that OTC warrants, OTC rights, OTC equity-linked notes, and OTC CVRs are providing debt or equity-oriented exposures or are received in connection with the Fund's previous investment in fixed income securities or equities. All of the other equity securities held by the Fund will comply with the requirements of Commentary .01(a)(1)(E) and (a)(2)(E) to NYSE Arca Rule 8.600–E. With respect to OTC CVRs, the Adviser represents that the Fund will not actively invest in such securities but may, at times, receive a distribution of such securities in connection with the Fund's holdings in other securities. Therefore, the Fund's holdings in OTC CVRs, if any, would not be utilized to further the Fund's investment objective and would not be acquired as the result of the Fund's voluntary investment decisions.

The Exchange accordingly believes that it is appropriate and in the public interest to approve listing and trading of Shares of the Fund on the Exchange notwithstanding that certain investments of the Fund would not meet the requirements of Commentary .01(a) and (b)(4) to Rule 8.600–E, as discussed above. The Exchange notes that, other than NYSE Arca Rule 8.600–E, Commentary .01(a)(1)(E) and .01(a)(2)(E) regarding OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs; Commentary .01(a)(1) regarding non-exchange-traded investment company securities; and Commentary .01(b)(4) regarding Private ABS/MBS, as described above, the Fund's portfolio will meet all other requirements of Rule 8.600–E, including the generic listing requirements in Commentary .01 to Rule 8.600–E.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that that holds fixed income securities, equity securities and derivatives and that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares of the Fund and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the PIV, the Disclosed Portfolio for the Fund, and quotation and last sale information for the Shares of the Fund.

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 purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that holds fixed income securities, equity securities and derivatives and that will enhance competition among market participants, to the benefit of investors and the marketplace.

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. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[46] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with Section 6(b)(5) of the Act,[47] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

According to the Exchange, other than Commentary .01(a)(1)(E) and .01(a)(2)(E) relating to OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs; Commentary .01(a)(1) relating to non-exchange-traded investment company securities; and Commentary .01(b)(4) relating to Private ABS/MBS, as described above, the Fund will meet all other requirements of Rule 8.600–E.

The Fund's investments in OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs will not comply with either Commentary .01(a)(1)(E) to Rule 8.600–E, which requires the U.S. Component Stocks in the portfolio to be listed on a national securities exchange and to be NMS Stocks, or Commentary .01(a)(2)(E) to Rule 8.600–E, which requires the Non-U.S. Component Stocks in the portfolio to be listed and traded on an exchange with last sale reporting. As proposed, the Fund may invest up to 15% of the Fund's assets in the aggregate in OTC equity-linked notes, OTC rights, OTC warrants, and OTC CVRs. The Exchange represents that the Fund will not actively invest in OTC CVRs but may, at times, receive a distribution of such securities in connection with the Fund's holdings in other securities. The Commission believes that the low level of investment by the Fund in such securities, *i.e.,* no more than 15% of the Fund's net assets, is not likely to make the Shares materially more susceptible to fraudulent or manipulative acts and practices.

With respect to the Fund's investments in shares of non-exchange-traded open-end management investment company securities, which will not comply with Commentary .01(a)(1) to Rule 8.600–E, the Commission notes that: (1) Such securities must satisfy applicable 1940 Act diversification requirements; and (2)

[46] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[47] 15 U.S.C. 78f(b)(5).

the value of such securities is based on the value of securities and financial assets held by those investment companies.[48] The Commission therefore believes that the Fund's investments in non-exchange-traded open-end management investment company securities would not make the Shares susceptible to fraudulent or manipulative acts and practices.

In addition, while the Fund will not meet the requirement that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria set forth in in Commentary .01(b)(4) to Rule 8.600–E, the Commission believes that the diversification of the Fund's portfolio, the limitation of Private ABS/MBS holdings to 20% of the weight of the portfolio, and the fact that the fixed income portion of the portfolio, excluding Private ABS/MBS, will comply with Commentary .01(b)(4), mitigate manipulation concerns relating to the Shares.

The Exchange represents that all statements and representations made in the filing regarding (a) the description of the portfolio holdings or reference assets, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in the rule filing constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor[49] for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with Section 6(b)(5) of the Act[50] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 3 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 3 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2019–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2019–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2019–36, and should be submitted on or before August 8, 2019.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 3

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 3, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 3 in the **Federal Register**. The Commission notes that Amendment No. 3 clarified the permitted investments of the Fund and the application of NYSE Arca Rule 8.600–E, Commentary .01 to the Fund's investments. Amendment No. 3 also provided other clarifications and additional information to the proposed rule change. The changes and additional information in Amendment No. 3 assist the Commission in evaluating the Exchange's proposal and in determining that it is consistent with the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[51] to approve the proposed rule change, as modified by Amendment No. 3, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[52] that the proposed rule change (SR–NYSEArca–2019–36), as modified by Amendment No. 3 be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15251 Filed 7–17–19; 8:45 am]

BILLING CODE 8011–01–P

[48] *See supra* Section II.C (Application of Generic Listing Standards).

[49] The Commission notes that certain proposals for the listing and trading of exchange-traded products include a representation that the exchange will ''surveil'' for compliance with the continued listing requirements. *See, e.g.,* Securities Exchange Act Release No. 77499 (April 1, 2016), 81 FR 20428, 20432 (April 7, 2016) (SR–BATS–2016–04). In the context of this representation, it is the Commission's view that ''monitor'' and ''surveil'' both mean ongoing oversight of compliance with the continued listing requirements. Therefore, the Commission does not view ''monitor'' as a more or less stringent obligation than ''surveil'' with respect to the continued listing requirements.

[50] 15 U.S.C. 78f(b)(5).

[51] 15 U.S.C. 78s(b)(2).

[52] *Id.*

[53] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a

submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before August 19, 2019.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: The Small Business Regulatory Enforcement Fairness Act of 1996, 15 U.S.C. Sec. 657(b)(2)(B), requires the SBA National Ombudsman to establish a means for SBA to receive comments on regulatory and compliance actions from small entities regarding their disagreements with a Federal Agency action. The Ombudsman uses it to obtain the agency's response, encourage a fresh look by the agency at a high level, and build a more small business-friendly regulatory environment.

Solicitation of Public Comments

Title: Federal Agency Comment Form.

Description of Respondents: Small Entities.

Form Number: 1993.

Estimated Annual Responses: 450.

Estimated Annual Hour Burden: 202.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–15308 Filed 7–17–19; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16031 and #16032; Missouri Disaster Number MO–00097]

Presidential Declaration of a Major Disaster for the State of Missouri

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Missouri (FEMA–4451–DR), dated 07/09/2019.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 04/29/2019 and continuing.

DATES: Issued on 07/09/2019.

Physical Loan Application Deadline Date: 09/09/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 04/09/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/09/2019, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Andrew, Atchison, Boone, Buchanan, Carroll, Chariton, Cole, Greene, Holt, Jackson, Jasper, Lafayette, Lincoln, Livingston, Miller, Osage, Pike, Platte, Pulaski, St. Charles.

Contiguous Counties (Economic Injury Loans Only):

Missouri: Audrain, Barton, Caldwell, Callaway, Camden, Cass, Christian, Clay, Clinton, Cooper, Dade, Dallas, Daviess, Dekalb, Franklin, Gasconade, Gentry, Grundy, Howard, Johnson, Laclede, Lawrence, Linn, Macon, Maries, Moniteau, Montgomery, Morgan, Newton, Nodaway, Pettis, Phelps, Polk, Ralls, Randolph, Ray, Saint Louis, Saline, Texas, Warren, Webster.

Iowa: Fremont, Page.

Illinois: Calhoun, Jersey, Madison, Pike.

Kansas: Atchison, Cherokee, Crawford, Doniphan, Johnson, Leavenworth, Wyandotte.

Nebraska: Nemaha, Otoe, Richardson.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.125
Homeowners without Credit Available Elsewhere	2.063
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16031C and for economic injury is 160320.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–15277 Filed 7–17–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16033 and #16034; Oregon Disaster Number OR–00099]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Oregon

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Oregon (FEMA–4452–DR), dated 07/09/2019.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 04/06/2019 through 04/21/2019.

DATES: Issued on 07/09/2019.

Physical Loan Application Deadline Date: 09/09/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 04/09/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on

07/09/2019, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Curry, Douglas, Grant, Linn, Umatilla, Wheeler.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 160336 and for economic injury is 160340.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–15276 Filed 7–17–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 16037 and # 16038; Missouri Disaster Number MO–00096]

Administrative Declaration of a Disaster for the State of Missouri

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Missouri dated 07/12/2019.

Incident: Severe Storms, Straight-line Winds and Flooding.

Incident Period: 03/11/2019 through 04/16/2019.

DATES: Issued on 07/12/2019.

Physical Loan Application Deadline Date: 09/10/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 04/13/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Andrew, Atchison, Buchanan, Holt.

Contiguous Counties:

Missouri: Clinton, DeKalb, Gentry, Nodaway, Platte.

Iowa: Fremont, Page.

Kansas: Atchison, Doniphan.

Nebraska: Nemaha, Otoe, Richardson.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.125
Homeowners without Credit Available Elsewhere	2.063
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16037 6 and for economic injury is 16038 0.

The States which received an EIDL Declaration # are Missouri, Iowa, Kansas, Nebraska.

(Catalog of Federal Domestic Assistance Number 59008)

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–15279 Filed 7–17–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15898 and #15899; Iowa Disaster Number IA–00086]

Presidential Declaration Amendment of a Major Disaster for the State of Iowa

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 8.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Iowa (FEMA–4421–DR), dated 03/23/2019.

Incident: Severe Storms and Flooding.

Incident Period: 03/12/2019 through 06/15/2019.

DATES: Issued on 07/09/2019.

Physical Loan Application Deadline Date: 07/16/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 12/23/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of IOWA, dated 03/23/2019, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Muscatine.

All counties contiguous to the above named county have previously been declared.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–15275 Filed 7–17–19; 8:45 am]

BILLING CODE 8026–03–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2019–0030]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes one extension, and revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents,

including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2019–0030].

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than September 16, 2019. Individuals can obtain copies of the collection instruments by writing to the above email address.

Work Incentives Planning and Assistance Program—0960–0629. As part of SSA's strategy to assist Social Security Disability Insurance (SSDI) beneficiaries and Supplemental Security Income (SSI) recipients who wish to return to work and achieve self-sufficiency, SSA established the Work Incentives Planning and Assistance (WIPA) program. This community based, work incentive, planning and assistance project collects identifying claimant information via project sites and community work incentives coordinators (CWIC). SSA uses this information to ensure proper management of the project, with particular emphasis on administration, budgeting, and training. In addition, project sites and CWIC's collect data from SSDI beneficiaries and SSI recipients on background employment, training, benefits, and work incentives. SSA is interested in identifying SSDI beneficiary and SSI recipient outcomes under the WIPA program, to determine the extent to which beneficiaries with disabilities and SSI recipients achieve their employment, financial, and healthcare goals. SSA will also use the data in its analysis and future planning for SSDI and SSI programs. Respondents are SSDI beneficiaries, SSI recipients, community project sites, and employment advisors.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Small Site (Under 150 beneficiaries served) (SSA–4565; SSA–4566; SSA–4567)	4,800	1	20	1,600
Medium Site (150–599 beneficiaries served) (SSA–4565; SSA–4566; SSA–4567)	7,500	1	20	2,500
Large Site (600 or more beneficiaries served) (SSA–4565; SSA–4566; SSA–4567)	17,700	1	20	5,900
Total Sites	30,000			10,000
SSDI & SSI Beneficiaries	30,000	1	25	12,500
Help Line	30,000	1	5	2,500
Total	90,000			25,000

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than August 19, 2019. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Real Property Current Market Value Estimate—0960–0471. SSA considers an individual's resources when evaluating eligibility for Supplemental Security Income (SSI) payments. The value of an individual's resources, including non-home real property, is one of the eligibility requirements for SSI payments. SSA obtains current market value estimates of the claimant's real property through Form SSA–L2794. We allow respondents to use readily available records to complete the form, or we can accept their best estimates. We use this form as part of initial applications and in post-entitlement situations. The respondents are small business operators in real estate; state and local government employees tasked with assessing real property values; and other individuals knowledgeable about local real estate values.

Type of Request: Extension of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–L2794	300	1	20	100

2. Child Care Dropout Questionnaire—20 CFR 404.211(e)(4)—0960–0474. If individuals applying for Title II disability benefits care for their own or their spouse's children under age 3, and have no steady earnings during the time they care for those children, they may exclude that period of care from the disability computation period. We call this the child-care dropout exclusion. SSA uses the information from Form SSA–4162 to determine if an individual qualifies for this exclusion. Respondents are applicants for Title II disability benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–4162	2,000	1	5	167

3. Medical Report on Adult with Allegation of Human Immunodeficiency Virus Infection; Medical Report on Child with Allegation of Human Immunodeficiency Virus Infection—20 CFR 416.933—20 CFR 416.934—0960–0500. Section 1631(e)(i) of the Social Security Act authorizes the Commissioner of SSA to gather information to make a determination about an applicant's claim for SSI payments; this procedure is the Presumptive Disability (PD). SSA uses Forms SSA–4814–F5 and SSA–4815–F6 to collect information necessary to determine if an individual with human immunodeficiency virus infection, who is applying for SSI disability benefits, meets the requirements for PD. The respondents are the medical sources of the applicants for SSI disability payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–4814–F5	9,600	1	8	1,280
SSA–4815–F6	80	1	10	13
Totals	9,680	.....	.....	1,293

4. Beneficiary Recontact Report—20 CFR 404.703 & 404.705—0960–0502. SSA investigates recipients of disability payments to determine their continuing eligibility for payments. Research indicates recipients may fail to report circumstances that affect their eligibility. Two such cases are: (1) When parents receiving disability benefits for their child marry; and (2) the removal of an entitled child from parents' care. SSA uses Form SSA–1588–SM to ask mothers or fathers about both their marital status and children under their care, to detect overpayments and avoid continuing payment to those are no longer entitled. Respondents are recipients of mothers' or fathers' Social Security benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1588–SM	76,944	1	5	6,412

5. Certification of Contents of Document(s) or Record(s)—20 CFR 404.715—0960–0689. SSA established procedures for individuals to provide the evidence necessary to establish their rights to Social Security benefits. Examples of such evidence categories include age, relationship, citizenship, marriage, death, and military service. Form SSA–704 allows SSA employees; State record custodians; and other custodians of evidentiary documents to certify and record information from original documents and records under their custodial ownership to establish these types of evidence. SSA uses Form SSA–704 in situations where individuals cannot produce the original evidentiary documentation required to establish benefits eligibility. The respondents are State record custodians and other custodians of evidentiary documents.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–704	293	1	10	49

6. Registration for Appointed Representative Services and Direct Payment—0960–0732. SSA uses Form SSA–1699 to register appointed representatives of claimants before SSA who:

- Want to register for direct payment of fees;
- Registered for direct payment of fees prior to 10/31/09, but need to update their information;
- Registered as appointed representatives on or after 10/31/09, but need to update their information; or
- Received a notice from SSA instructing them to complete this form.

By registering these individuals, SSA: (1) Authenticates and authorizes them to do business with us; (2) allows them to access our records for the claimants they represent; (3) facilitates direct payment of authorized fees to appointed representatives; and, (4) collects the information we need to meet Internal Revenue Service (IRS) requirements to

issue specific IRS forms if we pay an appointed representative in excess of a specific amount ($600). The respondents are appointed representatives who want to use Form SSA–1699 for any of the purposes cited in this Notice.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1699	17,700	1	20	5,900

7. Certificate of Incapacity—5 CFR 890.302(d)—0960–0739. Rules governing the Federal Employee Health Benefits (FEHB) plan require a physician to verify the disability of Federal employees' children ages 26 and over for these children to retain health benefits under their employed parents' plans. The physician must verify the adult child's disability: (1) Pre-dates the child's 26th birthday; (2) is very serious; and (3) will continue for at least one year. Physicians use Form SSA–604, the Certificate of Incapacity, to document and certify this information, and the Social Security Administration uses the information provided to determine the eligibility for these children, ages 26 and over, for coverage under a parent's FEHB plan. The respondents are physicians of SSA employees' children ages 26 or over who are seeking to retain health benefits under their parent's FEHB coverage.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–604	50	1	45	38

Dated: July 12, 2019.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2019–15249 Filed 7–17–19; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 10823]

Renewal of International Security Advisory Board

The Department of State announces the renewal of the Charter of the International Security Advisory Board (ISAB).

The purpose of the ISAB is to provide the Department with a continuing source of independent insight, advice, and innovation on all aspects of arms control, disarmament, nonproliferation, cybersecurity, the national security aspects of emerging technologies, and international security, and related aspects of public diplomacy. The ISAB will remain in existence for two years after the filing date of the Charter unless terminated.

For more information, please contact Christopher M. Herrick, Executive Director of the International Security Advisory Board, Department of State, Washington, DC 20520, telephone: (202) 647–9683.

(Authority: 41 CFR part 102–3.65)

Christopher M. Herrick,

Executive Director, International Security Advisory Board, Department of State.

[FR Doc. 2019–15285 Filed 7–17–19; 8:45 am]

BILLING CODE 4710–27–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1277X]

Savage Davenport Railroad Company—Discontinuance of Service Exemption—in Scott County, Iowa

On June 28, 2019, Savage Davenport Railroad Company (SDR) filed with the Board a petition under 49 U.S.C. 10502 for an exemption from the prior approval requirements of 49 U.S.C. 10903, to enable SDR to discontinue its operations over a rail line (the Line) owned by the City of Davenport, Iowa (the City), in Scott County, Iowa. The Line is approximately 2.8 miles long, extending from a switch near milepost 191.2 on the main line of a Canadian Pacific Railway subsidiary, west and south to the Davenport Transload Facility owned by the City. The Line traverses U.S. Postal Service Zip Code 52748.

According to SDR, the Line was constructed, and is owned, by the City [1] and is subject to a lease between the City and SDR, requiring SDR to provide common carrier rail service over the Line, serving industrial shippers.[2] SDR explains that it began operations on the Line in March of 2018, serving one rail customer and the Transload Facility. SDR states that the Transload Facility currently has zero activity. (Pet. 3 n.3.) SDR states that it has advised the City of its desire to discontinue service, and the City has raised no objection provided a suitable replacement is identified. (*Id.* at 3.) SDR states that, based on the information in SDR's possession, the Line does not contain federally granted rights-of-way. Any documentation in SDR's possession will be made available promptly to those requesting it.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

Because this is a discontinuance proceeding and not an abandonment proceeding, trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during any subsequent abandonment proceeding, this discontinuance does not require an

[1] *See City of Davenport—Construction & Operation Exemption—in Scott Cty., Iowa,* FD 35237 (STB served Apr. 6, 2011).

[2] *See Savage Davenport R.R.—Lease & Operation Exemption—City of Davenport,* FD 36142 (STB served Sept. 1, 2017).

environmental review. *See* 49 CFR 1105.8(b).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by October 16, 2019.

Any offer of financial assistance (OFA) for subsidy under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner.[3] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer by July 29, 2019, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(1)(i).

All filings in response to this notice must refer to STB Docket No. AB 1277X and must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on SDR's representative, Richard F. Riley, Jr., Foley & Lardner LLP, 3000 K Street NW, Suite 600, Washington, DC 20007–5109. Replies to the petition are due on or before August 7, 2019.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR. part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at 1–800–877–8339.

Board decisions and notices are available at *www.stb.gov.*

Decided: July 15, 2019.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–15288 Filed 7–17–19; 8:45 am]

BILLING CODE 4915–01–P

[3] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on a Request To Release Surplus Property at the Henry E. Rohlsen Airport, Christiansted, US Virgin Islands

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comment.

SUMMARY: Notice is being given that the Federal Aviation Administration (FAA) is considering a request from the Virgin Islands Port Authority to waive the requirement that 84.61 acres of surplus property located at the Henry E. Rohlsen Airport be used for aeronautical purposes. Currently, the ownership of the property provides for the protection of FAR Part 77 surfaces and compatible land use which would continue to be protected with deed restrictions required in the transfer of land ownership.

DATES: Comments must be received on or before August 19, 2019.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Rob Rau, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Ste. 220, College Park, GA 30337.

In addition, one copy of any comments submitted to the FAA must be mailed to: Damian Cartwright, P.E., Acting Executive Director, Virgin Islands Port Authority, P.O. Box 301707, St. Thomas, USVI 00803–1707.

FOR FURTHER INFORMATION CONTACT: Rob Rau, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Ste. 220, College Park, GA 30337, *robert.rau@faa.gov.* The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA is reviewing a request to release 84.61 acres of surplus property at the Henry E. Rohlsen Airport (STX) under the provisions of 49 U.S.C. 47151(d). On March 29, 2019, the Virgin Islands Port Authority requested the FAA release 84.61 acres of surplus property for commercial development. The FAA has determined that the proposed property release at the Henry E. Rohlsen Airport (STX), as submitted by the Virgin Islands Port Authority, meets the procedural requirements of the FAA and release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for aviation facilities at the Henry E. Rohlsen Airport.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at the Henry E. Rohlsen Airport.

Issued in Atlanta, GA, on July 11, 2019.

Larry F. Clark,

Manager, Atlanta Airports District Office.

[FR Doc. 2019–15224 Filed 7–17–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2019–0332]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: FAA Airport Master Record

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 2, 2019. The collection involves aeronautical information that the FAA uses to carry out agency missions related to aviation flying safety, flight planning, airport engineering and federal grants analysis, aeronautical chart and flight information publications, and the promotion of air commerce as required by statute. The information to be collected will be used for airspace studies conducted under 49 U.S.C. 329(b) and will be published in flight information handbooks and charts for pilot use.

DATES: Written comments should be submitted by August 19, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Andrew Goldsmith by email at: *Andrew.Goldsmith@faa.gov*; phone: 202–267–7669.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0015.

Title: FAA Airport Master Record.

Form Numbers: FAA Forms 5010–1, 5010–2, 5010–3, 5010–5.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 2, 2019 (84 FR 18916). 49 U.S.C. 329(b) empowers and directs the Secretary of Transportation to collect and disseminate information on civil aeronautics. Aeronautical information is required by the FAA to carry out agency missions related to aviation flying safety, flight planning, airport engineering and federal grants analysis, aeronautical chart and flight information publications, and the promotion of air commerce as required by statute. The safety information collected includes, but is not limited to, the following: Airport name, associated city, airport owner and airport manager, airport latitude, longitude, elevation, runway description, services available, runway approach light systems, communications frequency, airport use, number of operations and based aircraft, obstruction data, and pertinent general remarks. Airport owners/managers and state inspectors submit this information to the FAA.

Respondents: Approximately 9,037 Airport owners/managers and state inspectors.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden: 9,037 hours.

Issued in Washington, DC, on July 2, 2019.

Andrew Goldsmith,

Aeronautical Information Specialist, Airport Engineering Division, Office of Airport Safety and Standards.

[FR Doc. 2019–15302 Filed 7–17–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2019–0010]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the extension of a currently approved information collection: 49 U.S.C. Section 5310—Enhanced Mobility of Seniors and Individuals with Disabilities Program & Section 5311—Formula Grants for Rural Areas Program.

DATES: Comments must be submitted before September 16, 2019.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Website: www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site. (*Note:* The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *www.regulations.gov.* Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202–366–7951.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to *www.regulations.gov.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *www.regulations.gov.*

Docket: For access to the docket to read background documents and comments received, go to *www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Kelly Tyler, Office of Program Management (202) 366–3102 or email: *Kelly.Tyler@dot.gov.* Elan Flippin, Office of Program Management (202) 366–3800 or email *Elan.Flippin@dot.gov.*

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: 49 U.S.C. Section 5310—Enhanced Mobility of Seniors and Individuals With Disabilities Program & Section 5311—Formula Grants for Rural Areas Program (OMB Number: 2132–0500).

Background: 49 U.S.C. 5310 Enhanced Mobility of Seniors and Individuals with Disabilities Program provides financial assistance for the specialized transportation service needs of elderly persons and persons with disabilities in large urban, small urban and rural areas. Formula funding is apportioned to direct recipients: States for rural (under 50,000 population) and small urban (areas (50,000–200,000); and designated recipients chosen by the Governor of the State for large urban areas (populations or 200,000 or more); or a State or local governmental entity that operates a public transit service. Section 3006(b) of Fixing America's Surface Transportation Act (FAST Act), Public Law 114–94 authorized a pilot program for innovative coordinated access and mobility. 49 U.S.C. 5311—Formula Grants for Rural Areas Program provides financial assistance for the provision of public transportation services in rural areas. This program is administered by States. The Public Transportation on Indian Reservations Program or Tribal Transit Program (TTP), is authorized as 49 U.S.C. 5311(j). The TTP is a set-aside from the Rural Area Formula Program (Section 5311), and consists of a $30 million formula program and a $5 million competitive grant program. These funds are apportioned directly to Indian tribes. Eligible recipients of TTP program funds include federally recognized Indian tribes, or Alaska Native villages, groups, or communities as identified by the Bureau of Indian Affairs. 49 U.S.C. 5310 and 5311 authorize FTA to review applications for federal financial assistance to determine eligibility and compliance with statutory and administrative requirements. The applications must contain sufficient information to enable FTA to make the findings required by law to enforce the requirements of the programs. Information collected during the project management stage provides a basis for monitoring approved projects to ensure timely and appropriate expenditure of federal funds by grant recipients.

Respondents: State or local governmental entities that operates a public transportation service.

Estimated Annual Number of Respondents: 523 respondents.

Estimated Total Annual Burden: 54,727 hours.

Frequency: Annual.

Nadine Pembleton,

Director Office of Management Planning .

[FR Doc. 2019–15261 Filed 7–17–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2019–0013]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the extension of a currently approved information collection: National Transit Database 49 U.S.C. Section 5335(a)(b).

DATES: Comments must be submitted before September 16, 2019.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Website: www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site. (*Note:* The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *www.regulations.gov.* Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202–366–7951.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to *www.regulations.gov.* You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *www.regulations.gov.*

Docket: For access to the docket to read background documents and comments received, go to *www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Murtaza Naqvi, Office of Budget & Policy (202) 366–9285 or *Murtaza.Naqvi@dot.gov.*

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: National Transit Database (OMB Number: 2132–0008).

Background: 49 U.S.C. 5335(a) and (b) requires the Secretary of Transportation to maintain a reporting system, using a uniform system of accounts, to collect financial and operating information from the nation's public transportation systems. Congress created the NTD to be the repository of transit data for the nation to support public transportation service planning. FTA has established the NTD to meet these requirements, and has collected data for over 35 years. The NTD is comprised of four modules, Rural, Urban Annual, Monthly, and Safety Event Reporting. FTA continues to seek ways to reduce the burden of NTD reporting. FTA has added upload/download capabilities to the reporting system and greatly reduced the sampling required to certify Automatic Passenger Counters for use in reporting data to the NTD.

Respondents: State or local governmental entities that operates a public transportation service.

Estimated Annual Number of Respondents: 2,334 respondents.

Estimated Annual Number of Responses: 17,766.

Estimated Total Annual Burden: 327,524 hours.

Frequency: Annual.

Nadine Pembleton,

Director Office of Management Planning.

[FR Doc. 2019–15260 Filed 7–17–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0205]

Agency Information Collection Activity Under OMB Review: Application for Health Professions Trainees

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 19, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0205'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov.* Please refer to ''OMB Control No. 2900–0205'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Application for Health Professions Trainees, VA Form 10–2850D.

OMB Control Number: 2900–0205.

Type of Review: Extension of an approved collection.

Abstract: VA Form 10–2850D, Application for Health Professions Trainees, is part of a previously approved collection of forms under OMB control number 2900–0205. VA Form 10–2850D is designed specifically to elicit appropriate information about qualifications for each trainee participating in accredited educational programs with the Department of Veterans Affairs (VA). The 10–2850D form is used by all health professions trainees, including physician and dentist residents.

The collection of this information is authorized by 38 U.S.C. 7403 (Veterans' Benefits), which provides that appointments of Title 38 employees will be made only after qualifications have been satisfactorily verified in accordance with regulations prescribed by the Secretary. Occupations listed in 38 U.S.C. 7401(1) and 7401(3) (Appointments in Veterans Health Administration) are appointed at a grade and step rate, or an assignment, based on careful evaluation of their education and experience.

The Veterans Health Administration (VHA) conducts education and training programs through partnerships with affiliated academic institutions and through VHA's own sponsored programs. Qualified health care professionals with appropriate credentials and privileges supervise trainees. 38 U.S.C. 7302 (Functions of Veterans Health Administration: health-care personnel education and training programs) mandates that VHA assist in the training of health professionals for its own needs and for those of the nation.

The VA Form 10–2850D application will collect information from health professions trainees prior to VA appointment. All health professions trainees must provide information concerning their background, training, education, degrees, licensure, registrations, and other vital information to ensure appropriate qualifications for VA assignment.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 84 FR 19830 on May 6, 2019, pages 19830 and 19831.

Affected Public: Individuals or Households.

Estimated Annual Burden: 60,500 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 121,000.

By direction of the Secretary.

Danny S. Green,

Interim VA Clearance Officer, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs.

[FR Doc. 2019–15241 Filed 7–17–19; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 512

Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5527–P]

RIN 0938–AT89

Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement two new mandatory Medicare payment models under section 1115A of the Social Security Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model). The proposed RO Model would promote quality and financial accountability for providers and suppliers of radiotherapy (RT). The RO Model would test whether making prospective episode payments to hospital outpatient departments (HOPD) and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing Medicare program spending through enhanced financial accountability for RO Model participants. The proposed ETC Model would be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model would include ESRD facilities and certain clinicians caring for beneficiaries with ESRD—or Managing Clinicians—located in selected geographic areas as participants. CMS would assess the performance of participating Managing Clinicians and ESRD facilities on their rates of home dialysis and kidney and kidney-pancreas transplants during each Measurement Year (MY), and would subsequently adjust certain of their Medicare payments upward or downward during the corresponding performance payment adjustment period based on their home dialysis rate and transplant rate. CMS would also positively adjust certain Medicare payments to participating ESRD facilities and Managing Clinicians for home dialysis and home dialysis-related claims in the initial 3 years of the ETC Model.

We believe that these two proposed models would test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

DATES: *Comment period:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time on September 16, 2019.

ADDRESSES: In commenting, please refer to file code CMS–5527–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5527–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5527–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–8013.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Rebecca Cole (410) 786–1589. *Megan.Hyde@cms.hhs.gov,* for questions related to General Provisions. *RadiationTherapy@cms.hhs.gov,* for questions related to the Radiation Oncology Model. *ETC-CMMI@cms.hhs.gov,* for questions related to the ESRD Treatment Choices Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Publishing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/.*

Current Procedural Terminology (CPT) Copyright Notice

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I. Executive Summary

A. Purpose

The purpose of this proposed rule is to propose the implementation and testing of two new mandatory models under the authority of the Innovation Center, as well as to propose certain general provisions that would be applicable to both the RO Model and the ETC Model. Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. Under the Medicare fee-for-service (FFS) program, Medicare generally makes a separate payment to providers and suppliers for each item or service furnished to a beneficiary during the course of treatment. Because the amount of payments received by a provider or supplier for such items and services varies with the volume of items and services furnished to a beneficiary, some providers and suppliers may be financially incentivized to inappropriately increase the volume of items and services to receive higher payments. Medicare FFS may also detract from a provider's or supplier's incentive to invest in quality improvement and care coordination activities if it means those activities will result in a lower volume of items and

services. As a result, care may be fragmented, unnecessary, or duplicative.

The goal for the proposed models is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for model participants. We propose that the performance period of the proposed RO Model would begin in 2020, and end December 31, 2024. We propose to implement the proposed payment adjustments under the proposed ETC Model over the course of 6 and a half years, beginning January 1, 2020, and ending June 30, 2026.

The proposed models would offer participants the opportunity to examine and better understand their own care processes and patterns with regard to beneficiaries receiving RT services for cancer, and beneficiaries with ESRD, respectively. We chose these focus areas for the proposed models because, as discussed in depth in sections III and IV of this proposed rule, we believe that participants in these models would have significant opportunity to redesign care and improve the quality of care furnished to beneficiaries receiving these services.

We believe the proposed models would further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer or ESRD. Payments that are made to health care providers for assuming financial accountability for the cost and quality of care create incentives for the implementation of care redesign among model participants and other providers and suppliers.

CMS is testing several models, including voluntary models focused specifically on cancer and ESRD. The proposed RO and ETC Models would require the participation of providers and suppliers that might not otherwise participate in these models, and would be tested in multiple geographic areas.

The proposed models would allow CMS to test models with provider and supplier participation when there are differences in: (1) Historic care and utilization patterns; (2) patient populations and care patterns; (3) roles within their local markets; (4) volume of services; (5) levels of access to financial, community, or other resources; and (6) levels of population and health care provider density. We believe that participation in the proposed models by a large number of providers and suppliers with diverse characteristics would result in a robust data set for evaluating the models' proposed payment approaches and would stimulate the rapid development of new evidence-based knowledge. Testing the proposed models in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize quality improvement for beneficiaries receiving services for RT and ESRD, which could inform future model design.

We seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered.

B. Summary of the Major Proposed Provisions

1. General Provisions

The proposed general provisions would be applicable only to participants in the RO Model and the ETC Model. We have identified the proposed general provisions based on standardized parameters that have been repeatedly memorialized in various documents governing participation in existing model tests and propose to make them applicable to both proposed models so that we may eliminate repetition in the proposed 42 CFR part 512. The proposed general provisions address beneficiary protections, model evaluation and monitoring, audits and record retention, monitoring and compliance, remedial or administrative action, model termination by CMS, limitations on review, and miscellaneous provisions on bankruptcy and other notifications. These provisions are not intended to comprehensively encompass all the provisions that would apply to each model. Both the RO Model and the ETC Model have unique aspects that would require additional, more tailored provisions, including with respect to payment and quality measurement. Such model-specific provisions are described elsewhere in this proposed rule.

2. Model Overview—Proposed Radiation Oncology Model

In this proposed rule, we propose the creation and testing of a new payment model for radiation oncology, the RO Model. The intent of the proposed RO Model is to promote quality and financial accountability for episodes of care centered on RT services. The RO Model would test whether prospective episode-based payments to physician group practices (PGPs), HOPDs, and freestanding radiation therapy centers for RT episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the proposed RO Model would benefit Medicare beneficiaries by encouraging more efficient care delivery and incentivizing higher value care across episodes of care. We propose that the RO Model would have a performance period of five calendar years, beginning in 2020, and ending December 31, 2024. We propose to test the RO Model to capture all episodes that finish within the performance period, which means that the data collection, episode payments, and reconciliation would continue into calendar year 2025.

a. Summary of Major Provisions

(1) Proposed RO Model Overview

RT is a common treatment for patients undergoing cancer treatment and is typically furnished by a physician at either a HOPD or a freestanding radiation therapy center. We are proposing the RO Model to include prospective payments for certain RT services furnished during a 90-day episode for included cancer types for certain Medicare beneficiaries. The included cancer types would be determined by the following criteria: all are commonly treated with radiation; make up the majority of all incidence of cancer types; and have demonstrated pricing stability. (See section III.C.5.a of this proposed rule for more information.) This model would not account for total cost of all care provided to the beneficiary during the 90 days of an episode. Rather, the payment would cover only select RT services furnished during an episode. Episode payments would be split into two components—the professional component (PC) and the technical component (TC). This division reflects the fact that RT professional and technical services are sometimes furnished by separate providers and suppliers and paid for through different payment systems (namely, the Medicare Physician Fee Schedule and Outpatient Prospective Payment System).

For example, under the RO Model, a participating HOPD would have at least one PGP to furnish RT services at the HOPD. A PGP would furnish the PC as a professional participant and a HOPD would furnish the TC as a technical participant. Both would be participants in the RO Model, furnishing separate components of the same episode. A participant may also elect to furnish both the PC and TC as a Dual participant through one entity, such as a freestanding radiation therapy center. The proposed RO Model would test the

cost-saving potential of prospective episode payments for certain RT services furnished during a 90-day episode and whether shorter courses of RT (that is, fewer doses, also known as fractions) would encourage more efficient care delivery and incentivize higher value care.

(2) Model Scope

We propose criteria for the types of cancer included under the RO Model and list 17 cancer types that meet our proposed criteria. These cancer types are commonly treated with RT and, therefore, RT services for such cancer types can be accurately priced for purposes of a prospective episode payment model. RO Model episodes would include most RT services furnished in HOPDs and freestanding radiation therapy centers during a 90-day episode.

We propose that participation in the RO Model be mandatory for all RT providers and suppliers within selected geographic areas. We propose to use Core Based Statistical Areas (CBSAs) delineated by the Office of Management and Budget [1] as the geographic area for the randomized selection of RO participants. We would link RT providers and RT suppliers to a CBSA by using the five digit ZIP Code of the location where RT services are furnished permitting us to identify RO Model participants while still using CBSA as a geographic unit of selection. In addition, we propose to exclude certain providers and suppliers from participation under the model as described in section III.C.3.c. of this proposed rule.

We propose to include beneficiaries that meet certain criteria under the RO Model. For example, the proposed criteria would require that a beneficiary have a diagnosis of at least one of the cancer types included in the RO Model and that the beneficiary receive RT services from a participating provider or supplier in one of the selected CBSAs. Beneficiaries who meet these criteria would be included in the RO Model's episodes of care.

(3) Overlap With Other CMS Programs and Models

We expect that there could be situations where a Medicare beneficiary included in an episode under the RO Model is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among providers and suppliers at the individual or organization level, such as where a radiation oncologist or his or her PGP participates in multiple Innovation Center models. We believe that the RO Model is compatible with existing models and programs that provide opportunities to improve care and reduce spending, especially episode payment models like the Oncology Care Model. However, we would work to resolve any potential overlaps between the RO Model and other CMS models or programs that could result in repetitive services, or duplicative payment of services, and duplicative counting of savings or other reductions in expenditures.

(4) Episodes and Episode Pricing Methodology

We propose to set a separate payment amount for the PC and the TC of each of the cancer types included in the RO Model. The payment amounts would be determined based on proposed national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. The payment amount would also be adjusted for withholds for incomplete episodes, quality, and starting in performance year (PY) 3 beneficiary experience. The standard beneficiary coinsurance amounts (typically 20 percent of the Medicare-approved amount for services) and sequestration would remain in effect. RO participants would have the ability to earn back a portion of the quality and patient experience withholds based on their reporting of clinical data, their reporting and performance on quality measures, and as of PY3 performance on the beneficiary-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Radiation Therapy Survey.

(5) Quality Measures and Reporting Requirements

We propose to adopt four quality measures and collect the CAHPS® Cancer Care Radiation Therapy Survey for the RO Model. Three of the four measures that we are proposing are National Quality Forum (NQF)-endorsed process measures that are clinically appropriate for RT and are approved for the Merit-based Incentive Payment System (MIPS).[2] [3] We selected all proposed measures based on clinical appropriateness for RT services spanning a 90-day episode period. These measures would be applicable to the full range of proposed included cancer types and provide us the ability to accurately measure changes or improvements in the quality of RT services. Further, we believe that these measures would allow the RO Model to apply a pay-for-performance methodology that incorporates performance measurement with a focus on clinical care and beneficiary experience with the aim of identifying a reduction in expenditures with preserved or enhanced quality of care for beneficiaries.

We propose that RO participants would be paid for reporting clinical data in accordance with our proposed reporting requirements as discussed in section III.C.8.e, and paid for performance on aggregated quality measure data on three proposed quality measures and pay-for-reporting on one proposed quality measure (for PY1 and PY2) as discussed in section III.C.8.f. By PY3, we plan to propose to add a set of patient experience measures via rulemaking based on the CAHPS® Cancer Care Survey for Radiation Therapy for inclusion as pay-for-performance measures. We would also require Professional participants and Dual participants to report all quality data for all applicable patients receiving RT services from RO participants based on numerator and denominator specifications for each measure (for example, not just Medicare beneficiaries or beneficiaries receiving care for RT episodes under the RO Model).

(6) Data Sharing Process

We propose to collect quality, clinical, and administrative data for the RO Model. We intend to share certain data with participants to the extent permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We propose to establish data privacy compliance standards for RO participants. We propose to establish requirements around the public release of patient de-identified information by RO participants. We propose to offer RO participants the opportunity to request a claims data file that contains patient-identifiable data on the RO participant's patient population for clinical treatment, care management and coordination, and quality improvement activities. Also, we propose to permit the data to be reused by RO participants for provider incentive design and implementation, and we believe it may be of use in RO participants' review of our calculation of their participant-specific episode payment amounts and reconciliation

[1] See *https://www.census.gov/programs-surveys/metro-micro/about/omb-bulletins.html.*

[2] NQF endorsement summaries: *http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx.*

[3] See the CY 2018 QPP final rule (82 FR 53568).

payment amounts or recoupment amounts, as applicable. Thus, we expect that the data offered under the RO Model would be used by RO participants and CMS to better understand model effects, establish benchmarks, and monitor participant compliance. Again, as previously described, the data uses and sharing would be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law.

When using or disclosing such data, the RO participant would be required to make ''reasonable efforts to limit'' the information to the ''minimum necessary'' as defined by 45 CFR 164.502(b) and 164.514(d) to accomplish the intended purpose of the use, disclosure, or request. The RO participant would be required to further limit its disclosure of such information to what is permitted by applicable law, including the regulations promulgated under the HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) laws at 45 CFR part 160 and subparts A and E of part 164. Further discussion of data sharing can be found in section III.C.13 of this proposed rule.

(7) Beneficiary Protections

We propose to require professional participants and dual participants to notify RO beneficiaries of the beneficiary's inclusion in this model through a standardized written notice to each RO beneficiary during the treatment planning session. We intend to provide a notification template, which RO participants may personalize with contact information and logos, but must otherwise not be changed. Further explanation of the beneficiary notification can be found in section III.C.15. of this proposed rule.

(8) Program Policy Waivers

We believe it would be necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the RO Model under section 1115A(b) of the Act. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Each of the waivers is discussed in detail in section III.C.10. of this proposed rule, and proposed to be codified in our regulations at § 512.280.

3. Model Overview—Proposed ESRD Treatment Choices (ETC) Model

The proposed ETC Model would be a mandatory payment model, focused on encouraging greater use of home dialysis and kidney transplants for ESRD Beneficiaries among ESRD facilities and Managing Clinicians located in selected geographic areas. The proposed ETC Model would include two payment adjustments. The first adjustment, the Home Dialysis Payment Adjustment (HDPA), would be a positive adjustment on certain home dialysis and home dialysis-related claims during the initial three years of the model. The second adjustment, the Performance Payment Adjustment (PPA), would be a positive or negative adjustment on dialysis and dialysis-related Medicare payments, for both home dialysis and in-center dialysis, based on ESRD facilities' and Managing Clinicians' rates of kidney and kidney-pancreas transplants and home dialysis among attributed beneficiaries during the applicable MY. We propose to implement the payment adjustments under the ETC Model beginning January 1, 2020, and ending June 30, 2026.

a. Summary of Major Provisions

(1) Proposed ETC Model Overview

Beneficiaries with ESRD generally require some form of renal replacement therapy, the most common being hemodialysis (HD), followed by peritoneal dialysis (PD), or a kidney transplant. Most beneficiaries with ESRD receive HD treatments in an ESRD facility; however, other renal replacement modalities—including dialyzing at home or receiving a kidney transplant—may be better options than in-center dialysis for more beneficiaries than currently use them. We propose the ETC Model to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians—clinicians who bill the Monthly Capitation Payment (MCP) for managing ESRD Beneficiaries—to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. We believe ESRD facilities and Managing Clinicians are the key providers and suppliers managing the dialysis care and treatment modality options for ESRD Beneficiaries and have a vital role to play in beneficiary modality selection and assisting beneficiaries through the transplant process. We propose to adjust payments for home dialysis claims with claim through dates from January 1, 2020, through December 31, 2022 through the HDPA, and to assess the rates of home dialysis and kidney transplant among beneficiaries attributed to ETC Participants during the period beginning January 1, 2020, and ending June 30, 2025, with the PPA based on those rates applying to claims for dialysis and dialysis-related services with claim-through dates beginning January 1, 2021, and ending June 30, 2026.

(2) Model Scope

The proposed ETC Model would be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants for ESRD Beneficiaries. The rationale for a mandatory model for ESRD facilities and Managing Clinicians within selected geographic areas is that we seek to test the effect of payment incentives on availability and choice of treatment modality among a diverse group of providers and suppliers. We would randomly select Hospital Referral Regions (HRRs) for inclusion in the Model, and also include all HRRs with at least 20 percent of zip codes located in Maryland in addition to those selected through randomization. Managing Clinicians and ESRD facilities located in these selected geographic areas would be required to participate in the ETC Model and would be assessed on their rates of kidney and kidney-pancreas transplant and home dialysis among their attributed beneficiaries during each MY; CMS would then adjust certain of their Medicare payments upwards or downwards during the corresponding performance payment adjustment period. Managing Clinicians and ESRD facilities located in the selected geographic areas would also receive a positive adjustment on their home dialysis claims for the first three years of the ETC Model.

(3) Home Dialysis Payment Adjustment (HDPA)

We propose that CMS would make upward adjustments to the certain payments to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and would make upward adjustments to the MCP paid to participating Managing Clinicians on home dialysis claims. The HDPA would apply to claims with claims through dates beginning on January 1, 2020, and ending on December 31, 2022.

(4) Home Dialysis and Transplant Performance Assessment and Performance Payment Adjustment (PPA)

We propose to assess ETC Participants' rates of home dialysis and kidney and kidney-pancreas transplants during a MY, which would include 12 months of performance data. Each MY would overlap with the previous MY, if any, and the subsequent MY, if any, for a period of 6 months. Each MY would have a corresponding PPA Period—a 6-

month period, which would begin 6 months after the conclusion of the MY. CMS would adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate during the corresponding MY. We propose measuring rates of home dialysis and transplants for ESRD facilities and Managing Clinicians using Medicare claims data, Medicare administrative data including enrollment data, and the Scientific Registry of Transplant Recipients (SRTR) data. We propose to measure home dialysis rates for ESRD facilities and Managing Clinicians in the ETC Model by calculating the percent of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received dialysis at home. We propose to measure transplant rates for ESRD facilities and Managing Clinicians based on the number of attributed beneficiaries who received a kidney or kidney-pancreas transplant during the MY out of all attributed dialysis treatment beneficiary years (and attributed beneficiary years for pre-emptive transplant beneficiaries for Managing Clinicians) during the MY. For both Managing Clinicians and ESRD facilities, we propose to calculate the rates of home dialysis and kidney and kidney-pancreas transplants among attributed ESRD Beneficiaries. For Managing Clinicians, we propose to also include attributed beneficiaries who receive preemptive transplants—transplants that occur before the beneficiary begins dialysis—in the calculation of the transplant rate. We propose that the ETC Model would make upward and downward adjustments to certain payments to participating ESRD facilities under the ESRD PPS and to the MCP paid to participating Managing Clinicians based upon the ETC Participant's rates of home dialysis and transplants. The magnitude of the positive and negative PPAs for ETC Participants would increase over the course of the Model. These PPAs would begin July 1, 2021, and end June 30, 2026.

(5) Overlaps With Other Innovation Center Models and CMS Programs

The ETC Model would overlap with several other CMS programs and models, including initiatives specifically focusing on dialysis care. We believe the ETC Model would be compatible with other dialysis-focused CMS programs and models. However, we would work to resolve any potential overlaps between the ETC Model and other Innovation Center models or CMS programs that could result in repetitive services or duplicative payment of services. The payment adjustments made under the ETC Model would be counted as expenditures under the Medicare Shared Savings Program and other shared savings initiatives. Additionally, ESRD facilities would remain subject to the quality requirements in ESRD Quality Incentive Program (QIP), and Managing Clinicians who are MIPS eligible clinicians would remain subject to MIPS.

(6) Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA, we believe we would need to waive certain Medicare program rules. In particular, we would waive certain requirements of the Act for the ESRD PPS, ESRD QIP, and Medicare Physician Fee Schedule only to the extent necessary to make these payment adjustments under this proposed payment model for ETC Participants selected in accordance with CMS's proposed selection methodology. In addition, we propose that the payment adjustments made under the ETC Model, if finalized, would not change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part B services that were paid for beneficiaries who receive services from ETC Participants.

We also believe it would be necessary to waive certain Medicare payment requirements of 1861(ggg) of the Act and implementing regulations at 42 CFR 410.48, regarding the use of the Kidney Disease Education (KDE) benefit, solely for the purposes of testing the ETC Model. The purpose of such waivers would be to give ETC Participants additional access to the tools necessary to ensure beneficiaries select their preferred kidney replacement modality. As education is a key component of assisting beneficiaries with making such selections, we propose to waive select requirements regarding the provision of the KDE benefit, including waiving the requirement that certain health care provider types must furnish the KDE service to allow additional staff to furnish the service, waiving the requirement that the KDE service be furnished to beneficiaries with Stage IV CKD to allow ETC Participants to furnish these services to beneficiaries in later stages of kidney disease, and waiving certain restrictions on the KDE curriculum to allow the content benefit to be tailored to each beneficiary's needs.

We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act.

(7) Monitoring and Quality Measures

Consistent with the monitoring requirements proposed in the general provisions, we propose to closely monitor the implementation and outcomes of the ETC Model throughout its duration. The purpose of this monitoring would be to ensure that the ETC Model is implemented safely and appropriately, the quality or experience of care for beneficiaries is not harmed, and adequate patient and program integrity safeguards are in place.

As part of the monitoring strategy, we propose using two quality measures for the ETC Model: The Standardized Mortality Ratio and the Standardized Hospitalization Ratio. These measures are NQF-endorsed, and are currently calculated at the ESRD facility level for Dialysis Facility Reports and the ESRD QIP, respectively, and so would require no additional reporting by ETC Participants.

(8) Beneficiary Protections

As proposed, the ETC Model would not allow beneficiaries to opt out of the payment methodology; however, the model would not restrict a beneficiary's freedom to choose an ESRD facility or Managing Clinician, or any other provider or supplier, and ETC Participants would be subject to the general provisions protecting beneficiary freedom of choice and access to medically necessary services. We also would require that ETC Participants notify beneficiaries of the ETC Participant's participation in the ETC Model by prominently displaying informational materials in ESRD facilities and Managing Clinician offices or facilities where beneficiaries receive care. Additionally, ETC Participants would be subject to the general provisions regarding descriptive model materials and activities.

II. General Provisions

A. Introduction

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The Innovation Center has designed and tested numerous models governed by participation agreements, cooperative agreements, model-specific addenda to existing contracts with CMS, and regulations. While each of these models have a specific payment methodology, quality metrics, and certain other applicable policies, they also have general provisions that are

very similar, including provisions on monitoring and evaluation; compliance with model requirements and applicable laws; and beneficiary protections. We believe it would promote efficiency to propose and seek comment on certain general provisions in each of these areas that would apply to both the RO Model and the ETC Model in this section II of the proposed rule. This would avoid the need to restate the same provisions separately for the two models in this proposed rule. We propose to codify these general provisions in a new subpart of the Code of Federal Regulations (42 CFR part 512, subpart A).

B. Effective Date and Scope

In § 512.100(a), we propose that the proposed general provisions in this section II of the proposed rule would apply only to the RO Model and the ETC Model, each of which we are proposing to refer to as an ''Innovation Center model'' for purposes of this section II. of the proposed rule. These proposed general provisions would not, except as specifically noted in proposed new part 512, affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity (such as those in parts 413, 414, 419, 420, and 489 of chapter IV of 42 CFR and those in parts 1001–1003 of chapter V of 42 CFR).

In § 512.100(b), we propose that the proposed general provisions in this section II of the proposed rule would be applicable to model participants in both the RO Model (with one exception, described in this document) and the ETC Model. We are proposing to define the term ''model participant'' to mean an individual or entity that is identified as a participant in an Innovation Center model under the terms of proposed part 512; the term ''model participant'' as defined in this section II of the proposed rule includes, unless otherwise specified, the terms ''RO Model participant'' or ''ETC Participant'' as those terms are defined in proposed subparts B and C of proposed part 512. We propose to define ''downstream participant'' to mean an individual or entity that has entered into a written arrangement with a model participant pursuant to which the downstream participant engages in one or more Innovation Center model activities. A downstream participant may include, but would not be limited to, an individual practitioner, as defined for purposes of the RO Model. We propose to define ''Innovation Center model activities'' to mean any activities impacting the care of model beneficiaries related to the test of the Innovation Center model performed under the terms of proposed part 512. While not used in the general provisions described in this section II of the proposed rule, as this term is used for purposes of both the RO Model and the ETC Model, we propose to define ''U.S. Territories'' to mean American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

We invite public comment on the proposed general provisions discussed in this section II of the proposed rule.

C. Definitions

We propose at § 512.110 to define certain terms relevant to the general provisions proposed in this section II. of the proposed rule. We describe these proposed definitions in context throughout this section II. of the proposed rule.

D. Beneficiary Protections

As we design and test new models at the Innovation Center, we believe it is necessary to have certain protections in place to ensure that beneficiaries retain their existing rights and are not harmed by the participation of their health care providers in Innovation Center models. Therefore, we believe it is necessary to propose certain provisions regarding beneficiary choice, the availability of services, and descriptive model materials and activities.

For purposes of the general provisions, we are proposing to define the term ''beneficiary'' to mean an individual who is enrolled in Medicare FFS. This definition aligns with the proposed scope of the RO Model and the ETC Model, in which we propose to include only Medicare FFS beneficiaries. We also are proposing to define the term ''model beneficiary'' to mean a beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of this proposed part; the term ''model beneficiary'' as defined in this section would include, unless otherwise specified, the term ''RO Beneficiary'' and beneficiaries attributed to ETC participants under § 512.360. We believe it is necessary to propose this definition of model beneficiary so as to differentiate between Medicare FFS beneficiaries generally and those specifically included in an Innovation Center model.

1. Beneficiary Freedom of Choice

A beneficiary's ability to choose his or her provider or supplier is an important principle of Medicare FFS and is codified in section 1802(a) of the Act. To help ensure that this protection is not undermined by the testing of the two proposed Innovation Center models, we are proposing to codify at § 512.120(a)(1) a requirement that model participants and their downstream participants not restrict a beneficiary's ability to choose his or her providers or suppliers. The proposed policy would apply with respect to all Medicare FFS beneficiaries, not just model beneficiaries, because we believe it is important to ensure that the proposed Innovation Center model tests do not interfere with the general guarantees and protections for all Medicare FFS beneficiaries.

Also, we propose to codify at § 512.120(a)(2) that the model participant and its downstream participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any Medicare-participating provider or supplier, or from any health care provider who has opted out of Medicare. We believe this requirement is necessary to ensure Innovation Center models do not prevent beneficiaries from the general rights and guarantees provided under Medicare FFS. However, because we believe that it is important for model participants to have the opportunity to explain the benefits of care provided by them to model beneficiaries, we also are proposing that the model participant and its downstream participants would be permitted to communicate to model beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of proposed part 512 and applicable law.

We propose at § 512.110 to define the terms ''provider'' and ''supplier,'' as used in proposed part 512, in a manner consistent with how these terms are used in Medicare FFS generally. Specifically, we would define the term ''provider'' to mean a ''provider of services'' as defined under section 1861(u) of the Act and codified in the definition of ''provider'' at 42 CFR 400.202. We similarly propose to define the term ''supplier'' to mean a ''supplier'' as defined in section 1861(d) of the Act and codified at 42 CFR 400.202. We believe it is necessary to define ''provider'' and ''supplier'' in this way as a means of noting to the general public that we are using the generally

applicable Medicare definitions of these terms for purposes of proposed part 512.

2. Availability of Services

Models tested under the authority of section 1115A of the Act are designed to test potential improvements to the delivery of and payment for health care to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care for the beneficiaries of these programs. As such, an important aspect of testing Innovation Center models is that beneficiaries continue to access and receive needed care. Therefore, we are proposing in § 512.120(b)(1) that model participants and downstream participants would be required to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Consistent with the limitation on Medicare coverage under section 1862(a)(1)(A) of the Act, we propose to define ''medically necessary'' to mean reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. Also, we propose to define ''covered services'' to mean the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act, which aligns with Medicare coverage standards and the definition of ''covered services'' used in other models tested by the Innovation Center. Also, we propose that model beneficiaries and their assignees, as defined in 42 CFR 405.902, would retain their rights to appeal Medicare claims in accordance with 42 CFR part 405, subpart I. We believe that model beneficiaries and their assignees should not lose the right to appeal claims for Medicare items and services furnished to them solely because the beneficiary's provider or supplier is participating in an Innovation Center model.

Also, we are proposing in § 512.120(b)(2) to prohibit model participants and downstream participants from taking any action to avoid treating beneficiaries based on their income levels or based on factors that would render a beneficiary an ''at-risk beneficiary'' as that term is defined for purposes of the Medicare Shared Savings Program at 42 CFR 425.20, a practice commonly referred to as ''lemon dropping.'' For example, 42 CFR 425.20 defines an ''at-risk beneficiary'' to include, without limitation, a beneficiary who has one or more chronic conditions or who is entitled to Medicaid because of disability. As such, a model participant or downstream participant would be prohibited from taking action to avoid treating beneficiaries with chronic conditions such as obesity or diabetes, or who are entitled to Medicaid because of disability. We believe it is necessary to specify prohibitions on avoiding treating at-risk beneficiaries, including those with obesity or diabetes, or who are eligible for Medicaid because of disability, to prevent potential lemon dropping of beneficiaries. Further, we believe this proposal prohibiting lemon dropping is a necessary precaution to counter any incentives created by the proposed Innovation Center models for model participants to avoid treating potentially high-cost beneficiaries who are most in need of quality care. This prohibition has been incorporated into the governing documentation of many current models being tested by the Innovation Center for this same reason. Also, we are proposing in § 512.120(b)(3) an additional provision that would prohibit model participants from taking any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as ''cherry-picking.'' For example, a model participant or downstream participant would be prohibited from targeting only healthy, well educated, or wealthy beneficiaries for voluntary alignment, the receipt of permitted beneficiary incentives or other interventions, or the reporting of quality measures. Further, we are seeking comments on whether prohibiting cherry-picking will prevent model participants from artificially inflating their financial or quality performance results.

3. Descriptive Model Materials and Activities

In order to protect beneficiaries from potentially being misled about Innovation Center models, we are proposing at § 512.120(c)(1) to prohibit model participants and their downstream participants, from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. For purposes of proposed part 512, we propose to define the term ''descriptive model materials and activities'' to mean general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. We are further proposing that the following communications would not be descriptive model materials and activities: Communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of ''marketing'' as that term is defined at 45 CFR 164.501. The potential for model participants to receive certain payments under the two proposed Innovation Center models may be an incentive for model participants and their downstream participants to engage in marketing behavior that may confuse or mislead beneficiaries about the Innovation Center model or their Medicare rights. Therefore, we believe it is necessary to ensure that those materials and activities that are used to educate, notify, or contact beneficiaries regarding the Innovation Center model are not materially inaccurate or misleading because these materials might be the only information that a model beneficiary receives regarding the beneficiary's inclusion in the model. Additionally, we understand that not all communications between the model participant or downstream participants and the model beneficiaries would address the model beneficiaries' care under the model. As such, we would note that this proposed prohibition in no way restricts the ability of a model participant or its downstream participants to engage in activism or otherwise alert model beneficiaries to the drawbacks of mandatory models in which they would otherwise decline to participate, provided that such statements are not materially inaccurate or misleading. Because regulating information or communication not related to the model does not advance CMS's interest in ensuring model beneficiaries are not misled about their inclusion in an Innovation Center model or their Medicare rights generally, we have proposed to define the term ''descriptive model materials and activities'' such that these materials are not subject to the requirements of proposed § 512.120(c)(1).

Also, we propose in § 512.120(c)(4) to reserve the right to review, or have our designee review, descriptive model materials and activities to determine whether the content is materially inaccurate or misleading; this review would not be a preclearance by CMS, but would take place at a time and in

a manner specified by CMS once the materials and activities are in use by the model participant. We believe it would be necessary for CMS to have this ability to review descriptive model materials and activities in order to protect model beneficiaries from receiving misleading or inaccurate materials regarding the Innovation Center model. Further, to facilitate our ability to conduct this review and to monitor Innovation Center models generally, in proposed § 512.120(c)(3) we are proposing to require model participants and downstream participants, to retain copies of all written and electronic descriptive model materials and activities and to retain appropriate records for all other descriptive model materials and activities in a manner consistent with § 512.135(c) (record retention).

Also, we are proposing in § 512.120(c)(2) to require model participants and downstream participants to include the following disclaimer on all descriptive model materials and activities: ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.'' We are proposing to require the use of this disclaimer so that the public, and beneficiaries in particular, are not misled into believing that model participants or their downstream participants are speaking on behalf of the agency. We seek comment on whether we should propose a different disclaimer that alerts beneficiaries that we prohibit misleading information and give them contact information where a beneficiary could reach out to us if they suspect the information they have received regarding an Innovation Center model is inaccurate.

E. Cooperation With Model Evaluation and Monitoring

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential unintended or undesirable effects, such as cost-shifting. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act.

In addition to model evaluations, the Innovation Center regularly monitors model participants for compliance with model requirements. For the reasons described in section II.H of this proposed rule, these compliance monitoring activities are an important and necessary part of the model test.

Therefore, we are proposing to codify at § 512.130, that model participants and their downstream participants must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups. Additional details on the specific research questions that we propose that the Innovation Center model evaluation will consider for the Radiation Oncology Model and ESRD Treatment Choices Model can be found in sections III.C.16. and IV.C.11. of this proposed rule, respectively. Further, we propose to conduct monitoring activities according to proposed § 512.150, described later in this proposed rule, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually identifiable data.

F. Audits and Record Retention

By virtue of their participation in an Innovation Center model, model participants and their downstream participants may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility. Therefore, we believe that CMS's ability to audit, inspect, investigate, and evaluate records and other materials related to participation in Innovation Center models is necessary and appropriate. In addition, we are proposing in § 512.110 to require model participants and their downstream participants to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Similarly, in order to expand a phase 1 model tested by the Innovation Center, among other things, the Secretary must first determine that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. Thus, there is a particular need for CMS to be able to audit, inspect, investigate, and evaluate records and materials related to participation in Innovation Center models to allow us to ensure that model participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the Innovation Center model. We propose to define ''model-specific payment'' to mean a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers; the term ''model-specific payment'' would include, unless otherwise specified, the terms ''home dialysis payment adjustment (HDPA),'' ''performance payment adjustment (PPA),'' ''participant-specific professional episode payment,'' or ''participant-specific technical episode payment.'' We believe it is necessary to propose this definition in order to distinguish payments and payment adjustments applicable to model participants as part of their participation in an Innovation Center model, from payments and payment adjustments applicable to model participants as well as other providers and suppliers, as certain provisions of proposed part 512 would apply only to the former category of payments and payment adjustments.

We note that there are audit and record retention requirements under the Medicare Shared Savings Program (42 CFR 425.314) and in current models being tested under section 1115A (such as under 42 CFR 510.110 for the Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, we propose in § 512.135(a), that the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. Additionally, in order to align with the policy of current models being tested by

the Innovation Center, we are proposing in § 512.135(b) and (c) that the model participant and its downstream participants must:

• Maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the Innovation Center model, including, without limitation, documents and other evidence regarding all of the following:

++ Compliance by the model participant and its downstream participants with the terms of the Innovation Center model, including proposed new subpart A of proposed part 512.

++ The accuracy of model-specific payments made under the Innovation Center model.

++ The model participant's payment of amounts owed to CMS under the Innovation Center model.

++ Quality measure information and the quality of services performed under the terms of the Innovation Center model, including proposed new subpart A of proposed part 512.

++ Utilization of items and services furnished under the Innovation Center model.

++ The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

++ Patient safety.

++ Any other program integrity issues.

• Maintain the documents and other evidence for a period of 6 years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

++ There has been a termination, dispute, or allegation of fraud or similar fault against the model participant in which case the records must be maintained for an additional six (6) years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the model participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, we propose that the records must be maintained for such period of time determined by CMS. We also propose that, if CMS notifies the model participant of a special need to retain records or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, the model participant must notify its downstream participants of the need to retain records for the additional period specified by CMS. This provision will ensure that that the government has access to the records.

To avoid any confusion or disputes regarding the timelines outlined in this section II.G of the proposed rule, we propose to define the term ''days'' to mean calendar days.

We invite public comment on these proposed provisions regarding audits and record retention.

Historically, the Innovation Center has required participants in section 1115A models to retain records for at least 10 years, which is consistent with the outer limit of the statute of limitations for the Federal False Claims Act and is consistent with the Shared Savings Program's policy outlined at 42 CFR 425.314(b)(2). For this reason, we also solicit public comments on whether we should require model participants and downstream participants to maintain records for longer than 6 years.

G. Rights in Data and Intellectual Property

To enable CMS to evaluate the Innovation Center models as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to proposed § 512.150, described later in this rule, we are proposing to allow CMS to use any data obtained in accordance with proposed § 512.130 and proposed § 512.135 to evaluate and monitor the proposed Innovation Center models. We further propose that, consistent with section 1115A(b)(4)(B) of the Act, that CMS would be allowed to disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We propose that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources.

In order to protect the intellectual property rights of model participants and downstream participants, we propose in § 512.140(b) to require model participants and their downstream participants to label data they believe is proprietary that they believe should be protected from disclosure under the Trade Secrets Act. We would note that this approach is already in use in other models currently being tested by the Innovation Center, including the Next Generation Accountable Care Organization Model. Any such assertions would be subject to review and confirmation prior to CMS's acting upon such assertion.

We further propose to protect such information from disclosure to the full extent permitted under applicable laws, including the Freedom of Information Act. Specifically, in proposed § 512.140(b), we propose to not release data that has been confirmed by CMS to be proprietary trade secret information and technology of the model participant or its downstream participants without the express written consent of the model participant or its downstream participant, unless such release is required by law.

H. Monitoring and Compliance

Given that model participants may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility while participating in an Innovation Center model, we believe that enhanced compliance review and monitoring of model participants is necessary and appropriate to ensure the integrity of the Innovation Center model. In addition, as part of the Innovation Center's assessment of the impact of new Innovation Center models, we have a special interest in ensuring that model tests do not interfere with ensuring the integrity of the Medicare program. Our interests include ensuring the integrity and sustainability of the Innovation Center model and the underlying Medicare program, from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, as a part of the models currently being tested by the Innovation Center, CMS or its designee monitors model participants to assess compliance with model terms and with other applicable program laws and policies. We believe our monitoring efforts help ensure that model participants are furnishing medically necessary covered services and are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the model or are not in the best interests of the model, the Medicare program, or Medicare beneficiaries.

In proposed § 512.150(b), we propose to continue this standard practice of

conducting compliance monitoring activities to ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model, including the requirements of proposed subpart A of proposed part 512, including to understand model participants' use of model-specific payments and to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities would include, but not be limited to: (1) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires; (2) audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants; (3) interviews with members of the staff and leadership of the model participant and its downstream participants; (4) interviews with beneficiaries and their caregivers; (5) site visits to the model participant and its downstream participants, which would be performed in a manner consistent with proposed § 512.150(c), described later in this rule; (6) monitoring quality outcomes and registry data; and (7) tracking patient complaints and appeals. We believe these specific monitoring activities, which align with those currently used in other models being tested by the Innovation Center, are necessary in order to ensure compliance with the terms and conditions of the Innovation Center model, including proposed subpart A of proposed part 512, and to protect beneficiaries from potential harms that may result from the activities of a model participant or its downstream participants, such as attempts to reduce access to or the provision of medically necessary covered services.

We propose to codify in § 512.150(b)(2), that when we are conducting compliance monitoring and oversight activities, CMS or our designees would be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to model beneficiaries. We believe that it is necessary to have all relevant information available to us during our compliance monitoring and oversight activities, including any information already available to us through the Medicare program.

We propose to require in § 512.150(c)(1) that model participants and their downstream participants cooperate in periodic site visits conducted by CMS or its designee in a manner consistent with proposed § 512.130, described previously. Such site visits would be conducted to facilitate the model evaluation performed pursuant to section 1115A(b)(4) of the Act and to monitor compliance with the Innovation Center model terms (including proposed subpart A of proposed part 512).

In order to operationalize this proposal, we further propose in § 512.150(c)(2) that CMS or its designee would provide the model participant or its downstream participant with no less than 15 days advance notice of a site visit, to the extent practicable. Furthermore, we propose that, to the extent practicable, CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the model participant or downstream participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60 day period would reasonably accommodate model participant's and downstream participants' schedules while not interfering with the operation of the Innovation Center model. Further, we propose in § 512.150(c)(3) to require the model participant and their downstream participants to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. We believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Also, we are proposing in § 512.150(c)(4) that CMS or its designee could perform unannounced site visits to the offices of model participants and their downstream participants at any time to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues, notwithstanding these proposed provisions. Further, we propose in § 512.150(c)(5) that nothing in proposed part 512 would limit CMS from performing other site visits as allowed or required by applicable law. We believe that, regardless of the model being tested, CMS must always have the ability to timely investigate concerns related to the health or safety of beneficiaries or other patients, or program integrity issues, and to perform functions required or authorized by law. In particular, we believe that it is necessary for us to monitor, and for model participants and their downstream participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to beneficiaries in an attempt to change model results or their model-specific payments, including discrimination in the provision of services to at-risk beneficiaries (for example, due to eligibility for Medicaid based on disability).

Model participants that are enrolled in Medicare will remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the Innovation Center model. Therefore, in § 512.150(a), we propose to require that model participants and each of their downstream participants must comply with all applicable laws and regulations. We note that a law or regulation is not ''applicable'' to the extent that its requirements have been waived pursuant to section 1115A(d)(1) of the Act solely for purposes of testing the Innovation Center model in which the model participant is participating.

To protect the financial integrity of each Innovation Center model, we propose in § 512.150(d) that if CMS discovers that it has made or received an incorrect model-specific payment under the terms of an Innovation Center model, CMS may make payment to, or demand payment from, the model participant. Also, we are considering the imposition of some of the deadlines set forth in the Medicare reopening rules at 42 CFR 405.980, *et seq.;* specifically we seek comment on whether CMS should be able to reopen an initial determination of a model-specific payment for any reason within 1 year of the model-specific payment, and within 4 years for good cause (as defined at 42 CFR 405.986). We believe this may be necessary to ensure we have a means and a timeline to make redeterminations on incorrect model-specific payments that we have made or received in conjunction with the proposed Innovation Center models.

We propose to codify at § 512.150(e) that nothing contained in the terms of the Innovation Center model or proposed part 512 would limit or restrict the authority of the HHS Office of Inspector General (OIG) or any other Federal Government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants. This provision simply reflects the limits of CMS authority.

We invite public comment on these proposed provisions regarding monitoring of the proposed models and compliance by model participants.

I. Remedial Action

As stated earlier in this proposed rule, as part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A, we have a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, we monitor for compliance with model terms as well as other Medicare program rules. When we become aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

The terms of many models currently being tested by the Innovation Center permit CMS to impose one or more administrative remedial actions to address noncompliance by a model participant. We propose that CMS may impose any of the remedial actions set forth in proposed § 512.160(b) if we determine that the model participant or a downstream participant—

- Has failed to comply with any of the terms of the Innovation Center model, including proposed subpart A of proposed part 512, if finalized;
- Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- Has taken any action that threatens the health or safety of a beneficiary or other patient;
- Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model;
- Has undergone a change in control (as defined in section II.L. of this proposed rule) that presents a program integrity risk;
- Is subject to any sanctions of an accrediting organization or a Federal, state, or local government agency;
- Is subject to investigation or action by HHS (including the HHS–OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action; or
- Has failed to demonstrate improved performance following any remedial action imposed by CMS.

In § 512.160(b), we propose to codify that CMS may take one or more of the following remedial actions if CMS determined that one or more of the grounds for remedial action described in proposed § 512.160(a) had taken place—

- Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation;
- Require the model participant to provide additional information to CMS or its designees;
- Subject the model participant to additional monitoring, auditing, or both;
- Prohibit the model participant from distributing model-specific payments;
- Require the model participant to remove, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the Innovation Center model;
- In the ETC Model only, terminate the ETC Participant from the ETC Model;
- Require the model participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS;
- Discontinue the provision of data sharing and reports to the model participant;
- Recoup model-specific payments;
- Reduce or eliminate a model specific payment otherwise owed to the model participant, as applicable; or
- Such other action as may be permitted under the terms of proposed part 512.

We would note that because the ETC Model is a mandatory model, we would not expect to use the proposed provision that would allow CMS to terminate an ETC Participant's participation in the ETC Model, except in circumstances in which the ETC Participant has engaged, or is engaged in, egregious actions.

We invite public comment on these proposed provisions regarding the proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

J. Innovation Center Model Termination by CMS

We are proposing certain provisions that would allow CMS to terminate an Innovation Center model under certain circumstances. Section 1115A(b)(3)(B) of the Act requires the Innovation Center to terminate or modify the design and implementation of a model, after testing has begun and before completion of the testing, unless the Secretary determines, and the Chief Actuary certifies with respect to program spending, that the model is expected to: improve the quality of care without increasing program spending; reduce program spending without reducing the quality of care; or improve the quality of care and reduce spending.

We propose at § 512.165(a) that CMS could terminate an Innovation Center model for reasons including, but not limited to, the following circumstances:

- CMS determines that it no longer has the funds to support the Innovation Center model; or
- CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

As provided by section 1115A(d)(2)(E) of the Act and proposed § 512.170, termination of the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

To ensure model participants had appropriate notice in the case of the termination of the Innovation Center model by CMS, we also propose to codify at § 512.165(b) that we would provide model participants with written notice of the model termination, which would specify the grounds for termination as well as the effective date of the termination.

K. Limitations on Review

In proposed § 512.170, we propose to codify the preclusion of administrative and judicial review under section 1115A(d)(2) of the Act. Section 1115A(d)(2) of the Act states that there is no administrative or judicial review under section 1869 or 1878 of the Act or otherwise for any of the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites, or participants to test models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such section.

We propose to interpret the preclusion from administrative and judicial review regarding the Innovation Center's selection of organizations, sites, or participants to test models selected to preclude from administrative and judicial review our selection of a model participant, as well as our decision to terminate a model participant, as these determinations are part of our selection

of participants for Innovation Center model tests.

In addition, we propose to interpret the preclusion from administrative and judicial review regarding the elements, parameters, scope, and duration of models for testing or dissemination to preclude from administrative and judicial review the following CMS determinations made in connection with an Innovation Center model:

- The selection of quality performance standards for the Innovation Center model by CMS.
- The assessment by CMS of the quality of care furnished by the model participant.
- The attribution of model beneficiaries to the model participant by CMS, if applicable.

We invite public comment on the proposed codification of these statutory preclusions of administrative and judicial review for models, as well as our proposed interpretations regarding their scope.

L. Miscellaneous Provisions on Bankruptcy and Other Notifications

Models currently being tested by the Innovation Center usually have a defined period of performance, but final payment under the model may occur long after the end of this performance period. In some cases, a model participant may owe money to CMS. We recognize that the legal entity that is the model participant may experience significant organizational or financial changes during and even after the period of performance for an Innovation Center model. To protect the integrity of the proposed Innovation Center models and Medicare funds, we are proposing a number of provisions to ensure that CMS is made aware of events that could affect a model participant's ability to perform its obligations under the Innovation Center model, including the payment of any monies owed to CMS.

First, in proposed § 512.180(a), we propose that a model participant must promptly notify CMS and the local U.S. Attorney Office if it files a bankruptcy petition, whether voluntary or involuntary. Because final payment may not take place until after the model participant ceases active participation in the Innovation Center model or any other model in which the model participant is participating or has participated (for example, because the period of performance for the model ends, or the model participant is no longer eligible to participate in the model), we further propose that this requirement would apply until final payment has been made by either CMS or such model participant under the terms of each model in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

Specifically, we propose that notice of the bankruptcy must be sent by certified mail within 5 days after the bankruptcy petition has been filed and that the notice must contain a copy of the filed bankruptcy petition (including its docket number) and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. To minimize the burden on model participants, while ensuring that CMS obtains the information necessary from model participants undergoing bankruptcy, we propose that the list need not identify a model in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3–01–24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified for purposes of receiving such notices on the CMS website.

By requiring the submission of the filed bankruptcy petition, CMS would obtain information necessary to protect its interests, including the date on which the bankruptcy petition was filed and the identity of the court in which the bankruptcy petition was filed. We recognize that such notices may already be required by existing law, but CMS often does not receive them in a timely fashion, and they may not specifically identify the models in which the individual or entity is participating or has participated. The failure to receive such notices on a timely basis can prevent CMS from asserting a claim in the bankruptcy case. We are particularly concerned that a model participant may not furnish notice of bankruptcy after it has completed its performance in a model, but before final payment has been made or administrative or judicial proceedings have been resolved. We believe our proposal is necessary to protect the financial integrity of the proposed Innovation Center models and the Medicare Trust Funds. Because bankruptcies filed by individuals and entities that owe CMS money are generally handled by CMS regional offices, we are considering (and solicit comment on) whether we should require model participants to furnish notice of bankruptcy to the local CMS regional office instead of, or in addition to, the Baltimore headquarters.

Second, in proposed § 512.180(b), we propose that the model participant, including model participants that are individuals, would have to provide written notice to CMS at least 60 days before any change in the model participant's legal name became effective. The notice of legal name change would have to be in a form and manner specified by CMS and include a copy of the legal document effecting the name change, which would have to be authenticated by the appropriate state official. The purpose of this proposed notice requirement is to ensure the accuracy of our records regarding the identity of model participants and the entities to whom model-specific payments should be made or against whom payments should be demanded or recouped. We solicit comment on the typical procedure for effectuating a legal entity's name change and whether 60 days' advance notice of such a change is feasible. Alternatively, we are considering requiring notice to be furnished promptly (for example, within 30 days) after a change in legal name has become effective. We invite public comment on this alternative approach.

Third, in proposed § 512.180(c), we propose that the model participant would have to provide written notice to CMS at least 90 days before the effective date of any change in control. We propose that the written notification must be furnished in a form and manner specified by CMS. For purposes of this notice obligation, we propose that a ''change in control'' would mean any of the following: (1) The acquisition by any ''person'' (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the model participant by any individual or entity; (3) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant; or (4) the approval and completion of a plan of liquidation of the model participant, or an

agreement for the sale or liquidation of the model participant. The proposed requirement and definition of change in control are the same requirements and definition used in certain models that are currently being tested under section 1115A authority. We believe this proposed notice requirement is necessary to ensure the accuracy of our records regarding the identity of model participants and to ensure that we pay and seek payment from the correct entity. For this reason, we propose that if CMS determined in accordance with proposed § 512.160(a)(5) that a model participant's change in control would present a program integrity risk, CMS could take remedial action against the model participant under proposed § 512.160(b). In addition, to ensure payment of amounts owed to CMS, we propose that CMS may require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

We invite public comment on these proposed notification requirements. Also, we solicit comment as to whether the requirement to provide notice regarding changes in legal name and changes in control are necessary, or are already covered by existing reporting requirements for Medicare-enrolled providers and suppliers.

III. Proposed Radiation Oncology Model

A. Introduction

We are proposing a mandatory Radiation Oncology Model (RO Model), referred to in this section III. of the proposed rule as ''the Model,'' that would test whether prospective episode-based payments for radiotherapy (RT) services,[4] (also referred to as radiation therapy services) would reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under this proposed RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. The base payment amounts for RT services included in the Model would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. The performance period for the proposed RO Model would be five performance years (PYs), beginning in 2020, and ending December 31, 2024, with final data submission of clinical data elements and quality measures in 2025 to account for episodes ending in 2024.

We are including the following proposals for the Model in this proposed rule: (1) The scope of the Model, including required participants and episodes under the Model test; (2) the pricing methodology under the Model and necessary Medicare program policy waivers to implement such methodology; (3) the quality measures selected for the Model for purposes of scoring a participant's quality performance; (4) the process for payment reconciliation; and, (5) data collection and sharing.

B. Background

1. Overview

CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs. Accordingly, as part of that effort, we have in recent years undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model (OCM). We believe that a model in radiation oncology would further these efforts to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures.

RT is a common treatment for nearly two thirds of all patients undergoing cancer treatment [5] [6] and is typically furnished by a radiation oncologist. We analyzed Medicare FFS claims between January 1, 2015, and December 31, 2017, to examine several aspects (including but not limited to modalities, number of fractions, length of episodes, Medicare payments and sites of service, as described in this section) of radiation services furnished to Medicare beneficiaries during that period. We used HOPD and Medicare Physician Fee Schedule (PFS) claims, accessed through CMS's Chronic Conditions Data Warehouse (CCW), to identify all FFS beneficiaries who received any radiation treatment delivery services within that 3-year period. These radiation treatment delivery services included various types of modalities.[7] Such modalities included external beam radiotherapy (such as 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy), intraoperative radiotherapy (IORT), image-guided radiation therapy (IGRT), and brachytherapy. We conducted several analyses of radiation treatment patterns using that group of beneficiaries and their associated Medicare Part A and Medicare Part B claims.

Our analysis showed that from January 1, 2015 through December 31, 2017, HOPDs furnished 64 percent of episodes nationally, while freestanding radiation therapy centers furnished the remaining 36 percent of episodes. We intend to make this data publically accessible in a summary-level, de-identified file titled the ''RO Episode File (2015–2017),'' on the RO Model's website. Our analysis also showed that, on average, freestanding radiation therapy centers furnished (and billed for) a higher volume of RT services within such episodes than did HOPDs. Based on our analysis of Medicare FFS claims data from that time period, episodes of care in which RT was furnished at a freestanding radiation therapy center were, on average, paid approximately $1,800 (or 11 percent) more by Medicare than those episodes of care where RT was furnished at a HOPD. We are not aware of any clinical rationale that explains for these differences, which persisted after controlling for diagnosis, patient case mix (to the extent possible using data available in claims), geography, and other factors. These differences also persist even though Medicare payments are lower per unit in freestanding radiation therapy centers than in HOPDs. Upon further analysis, we observed that freestanding radiation therapy centers use more IMRT, a type of RT associated with higher Medicare payments, and perform more fractions (that is, more RT treatments) than HOPDs.

2. Site-Neutral Payments

Under Medicare FFS, RT services furnished in a freestanding radiation therapy center are paid under the

[4] *Radiotherapy (RT) services* (also referred to as radiation therapy services) are services associated with cancer treatment that use high *doses* of *radiation* to kill cancer *cells* and shrink tumors, and encompass treatment consultation, treatment planning, technical preparation and special services (simulation), treatment delivery, and treatment management.

[5] Physician Characteristics and Distribution in the U.5., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

[6] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

[7] Modality refers to various types of radiotherapy, which are commonly classified by the type of radiation particles used to deliver treatment.

Medicare PFS at the non-facility rate including payment for the professional and technical aspects of the services. For RT services furnished in an outpatient department of a hospital, the facility services are paid under the Hospital Outpatient Prospective Payment System (OPPS) and the professional services are paid under the PFS. Differences in the underlying rate-setting methodologies used in the OPPS and PFS to establish payment for RT services in the HOPD and in the freestanding radiation therapy centers respectively help to explain why the payment rate for the same RT service could be different. This difference in payment rate, which is commonly referred to as the site-of-service payment differential, may incentivize Medicare providers and suppliers to deliver RT services in one setting over another, even though the actual treatment and care received by Medicare beneficiaries for a given modality is the same in both settings. We propose to test a site-neutral payment in the RO Model rather than implementing a payment adjustment in the OPPS or PFS because—

• The Secretary of Health and Human Services does not have the authority to adjust payments outside of established payment methodologies under the Section 1848 governing the PFS;

• The Practice Expense (PE) component of the PFS is determined based on inputs (labor, equipment, and supplies) and input price estimates from entities paid under the PFS only, which means the PE calculation cannot consider HOPD cost data that the RO Model proposes to use as the basis for national base rates;

(1) • Further, the PE methodology itself calculates a PE amount for each service relative to all of the other services paid under the PFS in a budget neutral manner and consistent with estimates of appropriate division of PFS payments between PE, physician work, and malpractice resource costs; and

(2) • Both the PFS and OPPS make the same payment for a service, irrespective of the diagnosis, whereas the RO Model establishes different payments by cancer type.

(3) • Neither payment system would allow flexibility in testing new and comparable approaches to value-based payment outside of statutory quality reporting programs.

We believe a site-neutral payment policy would address the site-of-service payment differential that exists under the OPPS and PFS by establishing a common payment amount to pay for the same services regardless of where they are furnished. In addition, we believe that site-neutral payments would offer RT providers and RT suppliers more certainty regarding the pricing of RT services and remove incentives that promote the provision of RT services at one site of service over another. The RO Model is designed to test these assumptions regarding site-neutrality.

3. Aligning Payments to Quality and Value, Rather Than Volume

For some cancer types, stages, and characteristics, a shorter course of RT treatment with more radiation per fraction may be appropriate. For example, several randomized controlled trials have shown that shorter treatment schedules for low-risk breast cancer yield similar cancer control and cosmetic outcomes as longer treatment schedules.[8] [9] [10] [11] As another example, research has shown that radiation oncologists may split treatment for bone metastases into 5 to 10 fractions, even though research indicates that one fraction is often sufficient.[12] [13] [14] [15] In addition, recent clinical trials have demonstrated that, for some patients in clinical trials with low- and intermediate-risk prostate cancer, courses of RT lasting 4 to 6 weeks lead to similar cancer control and toxicity as longer courses of RT lasting 7 to 8 weeks.[16] [17]

Based on this review of claims data, we believe that the current Medicare FFS payment systems may incentivize selection of a treatment plan with a high volume of services over another medically appropriate treatment plan that requires fewer services. Each time a patient requires radiation, providers can bill for RT services and an array of necessary planning services to make the treatment successful.[18] This structure may incentivize providers and suppliers to furnish longer courses of RT because they are paid more for furnishing more services. Importantly, however, the latest clinical evidence suggests that shorter courses of RT for certain types of cancer would be equally effective and could improve the patient experience, potentially reduce cost for the Medicare program, and lead to reductions in beneficiary cost-sharing.

There is also some indication that the latest evidence-based guidelines are not incorporated into practices' treatment protocols in a timely manner.[19] For example, while breast cancer guidelines have since 2008 recommended that radiation oncologists use shorter courses of treatment for lower-risk breast cancer (3 weeks versus 5 weeks), an analysis found that, as of 2017, only half of commercially insured patients actually received the shorter course of treatment.[20]

4. CMS Coding and Payment Challenges

We identified several coding and payment challenges for RT services. Under the PFS, payment is set for each service using resource-based relative value units (RVUs). The RVUs have three components: Clinician work (Work), practice expense (PE), and

[8] Whelan, T.J. et al. Long-term Results of Hypofractionated Radiation Therapy for Breast Cancer. N. Engl. J. Med. 2010 Feb. 11; 362(6):513–20. *https://www.ncbi.nlm.nih.gov/pubmed/20147717.*

[9] Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial A of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. Lancet Oncol. 2008 Apr.; 9(4):331–41. *https://www.ncbi.nlm.nih.gov/pubmed/18356109.*

[10] Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial B of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. Lancet Oncol. 2008 Mar. 29; 371(9618): 1098–107. *https://www.ncbi.nlm.nih.gov/pubmed/18355913.*

[11] Haviland, J.S. et al. The UK Standardisation of Breast Radiotherapy (START) Trials of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: 10-Year Follow-Up Results of Two Randomised Controlled Trials. Lancet Oncol. 2013 Oct.; 14(11): 1086–94. *https://www.ncbi.nlm.nih.gov/pubmed/24055415.*

[12] Sze, W.M. et al. Palliation of Metastatic Bone Pain: Single Fraction Versus Multifraction Radiotherapy—A Systematic Review of The Randomised Trials. Cochrane Database Syst. Rev. 2004; (2):CD004721. *https://www.ncbi.nlm.nih.gov/pubmed/15106258.*

[13] Chow, E. et al. Update on the Systematic Review of Palliative Radiotherapy Trials for Bone Metastases. Clin. Oncol. (R. Coll. Radiol.). 2012 Mar; 24 (2):112–24. *https://www.ncbi.nlm.nih.gov/pubmed/22130630.*

[14] Chow, Ronald et al. Efficacy of Multiple Fraction Conventional Radiation Therapy for Painful Uncomplicated Bone Metastases: A Systematic Review. Radiotherapy & Oncology: March 2017 Volume 122, Issue 3, Pages 323–331. *http://www.thegreenjournal.com/article/S0167-8140(16)34483-8/abstract.*

[15] Lutz, Stephen et al. Palliative Radiation Therapy for Bone Metastases: Update of an ASTRO Evidence-Based Guideline. Practical Radiation Oncology (2017) 7, 4–12. *http://www.practicalradonc.org/article/S1879-8500(16)30122-9/pdf.*

[16] D. Dearnaley, I. Syndikus, H. Mossop, et al. Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-Year outcomes of the randomised, non-inferiority, phase 3 CHHiP trial. Lancet Oncol, 17 (2016), pp. 1047–1060. *http://www.sciencedirect.com/science/article/pii/S1470204516301024.*

[17] W.R. Lee, J.J. Dignam, M.B. Amin, et al. Randomized phase III noninferiority study comparing two radiotherapy fractionation schedules in patients with low-risk prostate cancer. J Clin Oncol, 34 (2016), pp. 2325–2332. *http://ascopubs.org/doi/full/10.1200/JCO.2016.67.0448.*

[18] These planning and technical preparation services include dose planning, treatment aids, CT simulations, and other services.

[19] *http://www.npr.org/sections/health-shots/2017/10/21/558837836/many-breast-cancer-patients-receive-more-radiation-therapy-than-needed.*

[20] *https://www.practicalradonc.org/cms/10.1016/j.prro.2018.01.012/attachment/775de137-63cb-4c5d-a7f9-95556340d0f6/mmc1.pdf.*

professional liability or malpractice insurance expense (MP). In setting the PE RVUs for services, we rely heavily on voluntary submission of pricing information for supplies and equipment, and we have limited means to validate the accuracy of the submitted information. As a result, it is difficult to establish the cost of expensive capital equipment, such as a linear accelerator, in order to determine PE RVUs for physicians' services that use such equipment.[21]

Further, we have examined RT services and their corresponding codes under our potentially misvalued codes initiative based on their high volume and increasing use of new technologies. Specifically, we reviewed codes for RT services for Calendar Years (CYs) 2009, 2012, 2013, and 2015 as potentially misvalued services. In general, when a code is identified as potentially misvalued, we finalize the code as misvalued and then review the Work and PE RVU inputs for the code. As a result of the review, the inputs can be adjusted either upward or downward. The criteria for identifying potentially misvalued codes are set forth in section 1848(c)(2)(K)(ii) of the Act.

Through annual rulemaking for the PFS, we review and adjust values for potentially misvalued services, and also establish values for new and revised codes. We establish Work and PE RVU inputs for new, revised, and potentially misvalued codes based on a review of information that generally includes, but is not limited to, recommendations received from the American Medical Association's RVS Update Committee (AMA/RUC), Health Care Professional Advisory Committee (HCPAC), Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; a comparison of the work for other codes within the PFS; and consultation with other physicians and health care professionals within CMS and other federal government agencies. We also consider the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

Through the annual rulemaking process previously described, we have reviewed and finalized payment rates for several RT codes over the past few years. The American Medical Association identified radiation treatment coding for review because of site of service anomalies. We first identified these codes as potentially misvalued services during CY 2012 under a screen called ''Services with Stand-Alone PE Procedure Time.'' We observed significant discrepancies between the 60-minute procedure time assumptions for IMRT. Public information suggested that the procedure typically took between 5 and 30 minutes. In CY 2015, the American Medical Association CPT® Editorial Panel revised the entire code set that describes RT delivery. CMS proposed values for these services in the CY 2016 proposed rule but, due to challenges in revaluing the new code set, finalized the use of G-codes that we established to largely mirror the previous radiation treatment coding structure.[22] The Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114–115), enacted on December 28, 2015, addressed payment for certain RT delivery and related imaging services under the PFS, and the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123) required the PFS to use the same service inputs for these codes as existed in 2016 for CY 2017, 2018, and 2019. (The PAMPA and BBA are discussed in detail in this rule).

Despite the aforementioned challenges related to information used to establish payment rates for RT services, we have systematically attempted to improve the accuracy of payment for these codes under the PFS. While the potentially misvalued code review process is essential to the PFS, some stakeholders have expressed concern that changes in Work and PE RVUs have led to fluctuations in payment rates. Occasionally, changes in PE RVUs for one or more CPT® codes occur outside of the misvalued code review cycle if there are updates to the equipment and supply pricing. Any changes to CPT® code valuations, including supply and equipment pricing changes, are subject to public comment and review.

Although the same code sets generally are used for purposes of the PFS and OPPS, there are differences between the codes used to describe RT services under the PFS and the OPPS, and those in commercial use more broadly. We continue to use some CMS-specific coding, or HCPCS codes, in billing and payment for RT services under the PFS while OPPS is largely based on CPT® codes. As a result of coding and other differences, these payment systems utilize different payment rates and reporting rules for the same services, which contribute to site-of-service payment differentials. These differences in payment systems can create confusion for RT providers and RT suppliers, particularly when they furnish services in both freestanding radiation therapy centers and HOPDs.

Finally, there are coding and payment challenges specific to freestanding radiation therapy centers. Through the annual PFS rulemaking process, we receive comments from stakeholders representing freestanding radiation therapy centers and physicians who furnish services in freestanding radiation therapy centers. In recent years, these stakeholder comments have noted the differences and complexity in payment rates and policies for RT services between the PFS and OPPS; expressing particular concerns about differences in payment for RT services furnished in freestanding radiation therapy centers and HOPDs despite that the fixed, capital costs associated with linear accelerators that are used to furnish these services do not differ across settings; and raising certain perceived deficiencies in the PFS rate-setting methodology as it applies to RT services delivered in freestanding radiation therapy centers.[23] It is also important to note that even if we were able to obtain better pricing information for inputs, due to the differing rate-setting methodologies, PFS rates are developed in relation to other PFS office-based services, not to OPPS payment rates.

As previously noted, the PAMPA addressed payment for certain RT delivery and related imaging services under the PFS. Specifically, section 3 of the PAMPA directed CMS to maintain the 2016 code definitions, Work RVU inputs, and PE RVU inputs for 2017 and 2018 for certain RT delivery and related imaging services; prohibited those codes from being considered as potentially misvalued codes for 2017 and 2018; and directed the Secretary to submit a Report to Congress on development of an episodic alternative payment model (APM) for Medicare payment for radiation therapy services furnished in non-facility settings. Section 51009 of the BBA of 2018 extended these payment policies through 2019. In November 2017, we submitted the Report to Congress as required by section 3(b) of the PAMPA.[24] In the report, we discussed the current status

[21] CY 2014 PFS final rule with comment period, 78 FR 43296, 43286–43289, 43302–43311.

[22] *See generally,* CY 2015 PFS final rule with comment period, 79 FR 67547; CY 2016 PFS final rule with comment period, 80 FR 70885; CY 2016 PFS correcting amendment, 81 FR 12024.

[23] *See generally,* CY 2018 PFS final rule with comment period, 82 FR 52976; CY 2015 PFS final rule with comment period, 79 FR 67547; CY 2014 PFS final rule with comment period, 78 FR 43296.

[24] *https://innovation.cms.gov/resources/radiationapm-pubforum.html.*

of RT services and payment, and reviewed model design considerations for a potential APM for RT services.

In preparing the Report to Congress, the Innovation Center conducted an environmental scan of current evidence, as well as held a public listening session followed by an opportunity for RT stakeholders to submit written comments about a potential APM. A review of the applicable evidence cited in the Report to Congress demonstrated that episode payment models can be a tool for improving quality of care and reducing expenditures. Episode payment models pay a fixed price based on the expected costs to deliver a bundle of services for a clinically defined episode of care. We believe that radiation oncology is a promising area of health care for episode payments, in part, based on the findings in the Report to Congress. While the report discusses several options for an APM, in this proposed rule, we propose what the Innovation Center has determined to be the best design for testing an episodic APM for RT services.

C. RO Model Proposed Regulations

In this proposed rule, we propose our policies for the RO Model, including model-specific definitions and the general framework for implementing the RO Model. We propose to define ''performance year'' (PY) as the 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period. We propose to codify the term ''performance year'' at § 512.205 of our regulations.

In this proposed rule, we are including our proposed policies for each of the following: (1) The scope of the RO Model, including the Model participants, beneficiary population, and RT episodes that would be included in the test; (2) the pricing methodology under the Model and the Medicare program policy waivers necessary to implement such methodology; (3) the measure selection for the model, including performance scoring methodology and applying quality to payment; (4) the process for payment reconciliation; and (5) data collection and sharing.

We propose to codify RO Model policies at 42 CFR part 512, subpart B (proposed §§ 512.200 through 512.290). In addition, as we explain in section II of this proposed rule, if finalized, the general provisions proposed to be codified at §§ 512.100 through 512.180 would apply to the proposed RO Model.

1. Proposed Model Performance Period

We propose to test the RO Model for 5 PYs. We propose to define ''model performance period'' to mean January 1, 2020, the date the Model begins, through December 31, 2024, the last date during which episodes under the Model must be completed. Alternatively, we are considering delaying implementation to April 1, 2020 to give RO participants and CMS additional time to prepare. An April 2020 start date would only affect the length of PY1 which would be nine months. All other PYs would be 12 months. For all episodes to be completed by December 31, 2024, no new episodes may begin after October 3, 2024. We invite public comments on the proposed model performance period and potential participants' ability to be ready to implement the RO Model by January 1, 2020. We also seek comments on delaying the start of the model performance period to April 1, 2020.

2. Proposed Definitions

We propose at § 512.205 to define certain terms for the RO Model. We describe these proposed definitions in context throughout this section III of this proposed rule. We invite public comments on these proposed definitions.

3. Proposed Participants

We propose that certain Medicare participating HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers that furnish RT services (RT providers or RT suppliers) in randomly selected Core-Based Statistical Areas (CBSAs), would be required to participate in the RO Model either as ''Professional participants,'' ''Technical participants,'' or ''Dual participants'' (as such terms are defined in section III.C.3.b of this proposed rule). We propose to define ''RO participant'' at § 512.205 as a PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to the criteria that we propose to establish at § 512.210. (See III.C.3.b Proposed RO Model Participants.) In addition, we note that the proposed definition of ''model participant,'' as defined in section III.C.3.b of this rule, would include a RO participant. In this section, we explain our proposals regarding mandatory participation, the types of entities that would be required to participate, and the geographic areas that would be subject to the RO Model test.

a. Proposed Required Participation

We propose that certain RT providers and RT suppliers that furnish RT services within randomly selected CBSAs would be required to participate in the RO Model (see III.C.3.b. of this proposed rule (Proposed RO Model Participants) and III.C.3.d. of this proposed rule (Geographic Unit of Section)). To date, the Innovation Center has tested one voluntary prospective episode payment model, Bundled Payments for Care Improvement (BPCI) Model 4 that attracted only 23 participants, of which 78 percent withdrew from the initiative. As such, we are interested in testing and evaluating the impact of a prospective payment approach for RT services in a variety of circumstances. We believe that by requiring the participation of RT providers and RT suppliers, we would have access to more complete evidence of the impact of the Model.

A representative sample of RT providers and RT suppliers for the proposed Model would result in a robust data set for evaluation of this prospective payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the Model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy. Therefore, we are proposing a broad, representative sample of RT providers and RT suppliers in multiple geographic areas (see Section III.C.3.d. of this proposed rule for a discussion regarding the Geographic Unit of Selection). We determined that the best method for obtaining the necessary diverse, representative group of RT providers and RT suppliers would be random selection. This is because a randomly selected sample would provide analytic results that would be more generally applicable to all Medicare FFS RT providers and RT suppliers and would allow for a more robust evaluation of the Model.

In addition, actuarial analysis suggests that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model. Further, actuarial estimates suggested that freestanding radiation therapy centers with historically lower RT costs compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to voluntarily participate. Requiring

participation in the RO Model would ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model.

For these reasons, we believe that a mandatory model design would be the best way to improve our ability to detect and observe the impact of the prospective episode payments made under the RO Model. We therefore propose that participation in the RO Model would be mandatory for all RT providers and RT suppliers furnishing RT services within the randomly selected CBSAs.

We invite public comments on our proposal for mandatory participation.

b. Proposed RO Model Participants

A RO participant, a term that we propose to define at § 512.205, would be a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that is required to participate in the RO Model pursuant to § 512.210. A RO participant would participate in the Model as a Professional participant, Technical participant, or Dual participant.

We propose to define the term ''Professional participant'' as a RO participant that is a Medicare-enrolled physician group practice (PGP), identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of RT services at either a freestanding radiation therapy center or a HOPD. Professional participants would be required annually to attest to the accuracy of an individual practitioner list, as described in section III.C.9, provided by CMS, of all of the eligible clinicians who furnish care under the Professional participant's TIN. We propose to define the term ''individual practitioner'' to mean a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and have reassigned his/her billing rights to the TIN of a RO participant. We further propose that an individual practitioner under the RO Model would be considered a downstream participant, as defined in section II.B. of this proposed rule.

We propose to define the term ''Technical participant'' to mean a RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the technical component of RT services. Finally, we propose to define ''Dual participant'' to mean a RO participant that furnishes for both the professional component and technical component of an episode for RT services through a freestanding radiation therapy center, identified by a single TIN. We propose to codify the terms ''Professional participant,'' ''Technical participant,'' ''Dual participant'' and ''individual practitioner'' at § 512.205.

As previously explained, a RO participant would furnish at least one component of an episode, which we are proposing to have two components: A professional component and a technical component. We propose to define the term ''professional component (PC)'' to mean the included RT services that may only be furnished by a physician. We propose to define the term ''technical component (TC)'' to mean the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and costs related to RT services. (See section III.C.5.c. of this proposed rule for a discussion regarding our proposed included RT services.) We propose to codify the terms ''professional component (PC)'' and ''technical component (TC)'' at § 512.205.

An episode of RT under the RO Model would be furnished by either: (1) Two separate RO participants, that is, a Professional participant that furnishes only the PC of an episode, and a Technical participant that furnishes only the TC of an episode; or (2) a Dual participant that furnishes both the PC and TC of an episode. For example, if a PGP furnishes only the PC of an episode at a HOPD that furnishes the TC of an episode, then the PGP would be a Professional participant and the HOPD would be a Technical participant. In other words, the PGP and HOPD would furnish separate components of the same episode and would be separate participants under the Model.

c. Proposed RO Model Participant Exclusions

We propose to exclude from RO Model participation any PGP, freestanding radiation therapy center, or HOPD that—

- Furnishes RT only in Maryland;
- Furnishes RT only in Vermont;
- Furnishes RT only in U.S. Territories;
- Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or
- Participates in or is identified as eligible to participate in the Pennsylvania Rural Health Model.

These exclusion criteria would apply during the entire model performance period. If a RO participant undergoes changes such that one or more of the proposed exclusion criteria becomes applicable to the RO participant during the model performance period, then that RO participant would be excluded from the RO Model (that is, it would no longer be a RO participant subject to inclusion criteria). For example, if a RO participant moves its only service location [25] from a randomly selected CBSA in Virginia to Maryland, it would be excluded from the RO Model from the date of its location change. Conversely, if a PGP, freestanding radiation therapy center, or HOPD satisfies the exclusion criteria when the Model begins, and subsequently experiences a change such that the proposed exclusion criteria no longer apply and the PGP, freestanding radiation therapy center, or HOPD is located in one of the randomly selected CBSAs, then participation in the RO Model would be required. For example, if an HOPD is no longer classified as a PPS-exempt hospital and the HOPD is located in one of the randomly selected CBSAs, then the HOPD would become an RO participant from the date that the HOPD became no longer classified as a PPS-exempt hospital.

In the case of Professional participants and Dual participants, any episodes in which the initial RT treatment planning service is furnished to a RO beneficiary on or after the day of this change would be included in the Model. In the case of Technical participants, any episodes where the RT service is furnished within 28 days of a RT treatment planning service for a RO beneficiary and the RT service is furnished on or after the day of this change would be included in the Model.

We propose to exclude RT providers and RT suppliers in Maryland due to the unique statewide payment model being tested there (the Maryland Total Cost of Care Model), in which Maryland hospitals receive a global budget. This global budget includes RT services and as such would overlap with the RO Model payment; thus, we propose to exclude Maryland HOPDs to avoid double payment for the same services. We propose to extend the exclusion to all RT providers and RT suppliers in Maryland to avoid creating a gaming opportunity where certain beneficiaries

[25] Service location means the site of service in which a RO Participant or any RT provider or RT supplier furnishes RT services.

could be shifted away from PGPs and freestanding centers to HOPDs.

We propose to exclude RT providers and RT suppliers in Vermont due to the Vermont All-Payer ACO Model, which is a statewide model in which all-inclusive population-based payments (AIPBPs) are currently made to the participating ACO for Medicare FFS services furnished by all participating HOPDs and an increasing number of participating PGPs. Given the scope of this model as statewide and inclusive of all significant payers, we believe excluding RT providers and RT suppliers in Vermont from the RO Model is appropriate to avoid any potential interference with the testing of the Vermont All-Payer ACO Model.

We propose to exclude HOPDs that are participating in or eligible to participate in the Pennsylvania Rural Health Model. HOPDs that are participating in the model receive a global budget similar to the Maryland Total Cost of Care Model. Further, we propose to extend the exclusion to HOPDs that are eligible to participate in the Pennsylvania Rural Health Model because they may be added to that model in the future or may be included in the evaluation comparison group for that model. We would identify the CAHs and acute care hospitals that are participating or are eligible to participate in the Pennsylvania Rural Health Model on a list to be updated quarterly and made available on the Pennsylvania Rural Health Model's website at *https://innovation.cms.gov/initiatives/pa-rural-health-model/.*

The proposed RO Model is designed to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures by providing savings for Medicare while preserving or enhancing quality. We believe it would be inappropriate to include these entities for the reasons previously described. Also, we are proposing to exclude ASCs and RT providers and RT suppliers located in the U.S. Territories, as proposed at § 512.210, due to the low volume of RT services that they provide. In addition, we are proposing to exclude CAHs and PPS-exempt cancer hospitals due to the differences in how they are paid by Medicare.

As a result, we propose that RT services furnished by these RT providers and RT suppliers would be excluded from participation in the RO Model. If in the future we determine that providers and suppliers in these categories should be included in the RO Model, we would propose to revise our inclusion criteria through rulemaking.

We further propose to codify these policies at § 512.210 of our regulations.

We invite public comments on these proposals.

d. Proposed Geographic Unit of Selection

We propose that the geographic unit of selection for the RO Model would be OMB's Core Based Statistical Areas (CBSAs). Due to geographic data limitations on Medicare claim submissions, we would link RT providers and RT suppliers to a CBSA by using the five-digit ZIP Code of the location where RT services are furnished. This would permit us to identify RO Model participants (see section III.C.3.c. of this proposed rule RO Model Participant Exclusions for the RT providers and RT suppliers we are proposing to exclude from the RO Model) while still using CBSA as a geographic unit of selection. We further propose to codify the term ''Core Based Statistical Area (CBSA)'' at § 512.205 of our regulations.

CBSAs are delineated by the Office of Management and Budget and published on *Census.gov*.[26] A CBSA is a statistical geographic area with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core). CBSAs are ideal for use in statistical analyses because they are sufficiently numerous to allow for a robust evaluation and are also large enough to reduce the number of RO participants in close proximity to other RT providers and RT suppliers that would not be required to participate in the Model. CBSAs do not include the extreme rural regions, but there are very few RT providers and RT suppliers in these areas such that, if included, the areas would likely not generate enough episodes to be included in the statistical analysis; further, CBSAs do contain rural RT providers and RT suppliers as designated by CMS and Health Resources and Services Administration (HRSA). Therefore, CBSAs would capture the diversity of RT providers and RT suppliers who may be affected by the RO Model, and as such, we do not propose to include non-CBSA geographies in the RO Model test.

However, most RT providers and RT suppliers may not know in what CBSA they furnish RT services. In order to simplify the notification process to inform RT providers and RT suppliers whether or not they furnish RT services in a selected CBSA, we are proposing to use an RT provider's or RT supplier's service location five-digit ZIP Code found on the RT provider's or RT supplier's claim submissions to CMS to link them to CBSAs selected under the Model.

Not all five-digit ZIP Codes fall entirely within OMB delineated CBSA boundaries, resulting in some five-digit ZIP Codes assigned to two different CBSAs. Approximately 15 percent (15 percent) of five-digit ZIP Codes have portions of their addresses located in more than one CBSA. If each ZIP Code was assigned only to the CBSA with the largest portion of delivery locations in it, about 5 percent of all delivery locations in ZIP Codes would be assigned to a different CBSA. Rather than increase provider burden by requiring submission of more detailed geographic data by RT providers and RT suppliers, we propose to assign the entire five-digit ZIP Code to the CBSA where the ZIP code has the greatest portion of total addresses (business, residence, and other addresses) such that each five-digit ZIP Code is clearly linked to a unique CBSA or non-CBSA geography. In the event that the portion of total addresses within the five-digit ZIP Code is equal across CBSAs and cannot be used to make the link, the greater portion of business addresses would take precedence to link the five-digit ZIP Code to the CBSA.

CMS would use a five-digit ZIP Code to CBSA crosswalk found in the Housing and Urban Development (HUD) ZIP to CBSA Crosswalk file[27] to link each five-digit ZIP Code to a single CBSA. The HUD ZIP to CBSA Crosswalk file lists the ZIP Codes (which come from the United States Postal Service) that correspond with the CBSAs (which are Census Bureau geographies) in which those ZIP Codes exist, allowing these two methods of geographic identification to be linked.

We believe that linking a five-digit ZIP Code to a single CBSA would not substantially impact statistical estimates for the RO Model. In addition, we believe that using a service location's five-digit ZIP Code to determine

[26] See OMB Bulletin No. 18–04 entitled ''Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas,'' *https://www.census.gov/programs-surveys/metro-micro/about/omb-bulletins.html.*

[27] Datasets and documentation for HUD USPS Zip Code Crosswalk Files (which includes the above mentioned HUD ZIP–CBSA crosswalk file) can be found here: *https://www.huduser.gov/portal/datasets/usps_crosswalk.html.*

whether an RT provider or RT supplier must participate in the Model will avoid potential RT provider or RT supplier burden by avoiding an additional requirement that they submit claims using more detailed geographic information. If finalized as proposed, CMS would provide a look-up tool that includes all five-digit ZIP Codes linked to CBSAs selected in accordance with our proposed selection policy described in this proposed rule. This tool would be located on the RO Model website.

Using CBSAs to identify RO participants would enable CMS to analyze groups of RT providers and RT suppliers in areas selected to participate in the Model and compare them to groups of RT providers and RT suppliers not participating in the Model. To the extent that CBSAs act like or represent markets, these group analyses would allow CMS to observe potential group level, market-like effects. We have found group level effects important as context for understanding the results of other models tested under section 1115A of the Act. For example, stakeholders questioned whether a model changed the overall volume of services related to the specific model in a given area. We would not be able to address this issue for the RO Model without using a geographic area as the unit of analysis.

With respect to selecting CBSAs under the Model, we propose to use a stratified sample design based on the observed ranges of episode counts in CBSAs using claims data from calendar years 2015–2017. We would then randomize the CBSAs within each stratum into participant and comparison groups until the targeted number of RO episodes within each group of CBSAs needed for a robust [28] test of the Model is reached. The primary purpose of the evaluation is to estimate the impact of the Model across all participating organizations. Larger sample sizes decrease the chances that the evaluation would produce mistakes, that is show 'no effect' when an effect is actually present (like an instance when a smoke detector fails to sound an alarm even though smoke is actually present) or show 'an effect' when no effect is actually present (like an instance when a smoke detector is sounding an alarm that suggests smoke is detected when actually no smoke is present). Given that we plan to sample 40 percent of all eligible RO episodes in eligible CBSAs nationwide (as defined in section III.C.5 of this proposed rule), we believe we should be sufficiently powered (that is, the sample size and the expected size of the effect of the Model are both large enough at a given significance level) to confidently show the impact of the Model. The comparison group would consist of RT providers and RT suppliers from randomized CBSAs within the same strata as the selected RO participants from the participant group, resulting in a comparison group of an approximately equal number of CBSAs and episodes as in the participant group that would allow for the effects of the RO Model to be evaluated. Strata will be divided into five quintiles based on the total number of episodes within a given CBSA. The stratification would limit uneven RT provider and RT supplier and episode numbers within the participant and comparison groups of CBSAs that can result from a simple random sample. If a CBSA is randomly assigned to the participant group, then the RT providers and RT suppliers who furnish RT services in that CBSA would be RO participants. If the CBSA is randomly assigned to the comparison group, then the providers and suppliers who furnish RT services in that CBSA would not be RO participants, but the claims they generate and the episodes constructed from those claims would be used as part of the RO Model's evaluation.

After determining the sampling framework, we conducted the necessary power calculations (statistical tests to determine the minimum sample size of the participant and comparison groups in the Model, designed in order to produce robust and reliable results) using Medicare FFS claims from January 1, 2015 through December 31, 2017, to construct episodes and then identify a sufficient sample size so that results would be precise and reliable. We determined that 40 percent of eligible episodes (as defined in section III.C.5 of this proposed rule) in eligible CBSAs nationally would allow for a rigorous test of the RO Model that would produce evaluation results that we can be confident are accurately reflecting what actually occurred in the Model test, and that this size would limit the number of episodes expected in the participant group to no more than is needed for a robust statistical test of the projected impacts of the Model.

Using randomly selected stratified CBSAs would ensure that the participant and comparison groups of CBSAs would each contain approximately 40 percent of all eligible episodes nationally. The comparison group of CBSAs would be used to evaluate the impact of the RO Model on spending, quality, and utilization. The CBSAs would be randomly selected and those CBSAs and the ZIP Codes selected for participation would be published on the RO Model website once the final rule is displayed.

4. Proposed Beneficiary Population

We propose that a Medicare FFS beneficiary be included in the RO Model if the beneficiary:

- Receives included RT services in a five-digit ZIP Code linked to a selected CBSA from a RO participant during the model performance period for a cancer type that meets the criteria for inclusion in the RO Model; and
- At the time that the initial treatment planning service of the episode is furnished by a RO participant, the beneficiary:

++ Is eligible for Medicare Part A and enrolled in Medicare Part B; and

++ Has traditional Medicare FFS as his or her primary payer.

In addition, we propose to exclude from the RO Model any beneficiary who, at the time that the initial treatment planning service of the episode is furnished by a RO participant:

- Is Enrolled in any Medicare managed care organization, including but not limited to Medicare Advantage plans;
- Is Enrolled in a PACE plan;
- Is not in a Medicare hospice benefit period; or
- Is covered under United Mine Workers.

Because the RO Model would evaluate RT services furnished to beneficiaries who have been diagnosed with one of the cancer types identified as satisfying our proposed criteria for inclusion in the Model, as discussed in section III.C.5.a, we believe it would be necessary to include only beneficiaries who have at least one of the identified cancer types and who also receive RT services from RO participants. Further, a key objective of the RO Model would be to evaluate if and/or how RT service delivery changes in either the HOPD or freestanding radiation therapy center setting as a result of a change in payment systems from that of FFS under OPPS or PFS, respectively, to that of prospectively determined bundled rates for an episode of RT services as described in section III.C.6.c. We propose these criteria in order to limit RT provider and RT supplier participation in the RO Model to beneficiaries whose RT providers and RT suppliers would otherwise be paid by way of traditional FFS payments for the identified cancer types. We believe that these eligibility criteria for RO

[28] 'Robust' in statistical terminology means that we can have high confidence in the test results under a broad range of conditions, for example, lower quality data, a shortened test period, or other unexpected complications.

beneficiaries are necessary in order to properly evaluate this change with minimal intervening effects.

We propose that a beneficiary who meets all of these criteria, and who does not trigger any of the beneficiary exclusion criteria, would be called a ''RO beneficiary''. We propose to codify the terms ''RO beneficiary,'' ''RT provider,'' and ''RT supplier'' at § 512.205.

In addition, we propose to include in the RO Model any beneficiary participating in a clinical trial for RT services for which Medicare pays routine costs, provided that such beneficiary meets all of the proposed beneficiary inclusion criteria. We would consider routine costs of a clinical trial to be all items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.[29] Medicare pays routine costs by way of FFS payments, making it appropriate to include RT services furnished for RO episodes in this case under the RO Model.

The RO Model's proposed design would not allow RO beneficiaries to ''opt out'' of the Model's pricing methodology. A beneficiary who is included in the RO Model pursuant to the previously proposed criteria would have his or her RT services paid for under the Model's pricing methodology and would be responsible for the coinsurance amount as described in section III.C.6.i. Beneficiaries do have the right to choose to receive RT services in a geographic area not included in the RO Model.

If a RO beneficiary stops meeting any of the proposed eligibility criteria or triggers any of the exclusion criteria (see section III.C.4. of this proposed rule) before the TC of an episode initiates, then the episode would be an incomplete episode as described in section III.C.6.a. of this proposed rule Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11. of this proposed rule.

If traditional Medicare stops being an RO beneficiary's primary payer after the TC of the episode has been initiated, then regardless of whether the beneficiary's course of RT treatment was completed, the 90-day period would be considered an incomplete episode and, the RO participant would receive only the first installment of the episode payment. In the event that a beneficiary dies or enters hospice during an episode, then the RO participant would receive both installments of the episode payment, regardless of whether the RO beneficiary's course of RT has ended (see section III.C.7. of this proposed rule).

We are proposing these beneficiary eligibility criteria for purposes of determining beneficiary inclusion in and exclusion from the Model.

5. Proposed RO Model Episodes

In this proposed RO Model, Medicare would pay RO participants a site-neutral, episode-based payment amount for all specified RT services furnished to a RO beneficiary during a 90-day episode. In this section, we first explain our proposal to include criteria to add or remove cancer types under the Model and their relevant diagnoses codes in the Model as well as the RT services and modalities that would be covered and not covered in an episode payment for treatment of those cancer types. We then explain our proposal for testing a 90-day episode and propose the conditions that must be met to trigger an episode.

a. Proposed Included Cancer Types

We propose the following criteria for purposes of including cancer types under the RO Model. The cancer type—

- Is commonly treated with radiation; and
- Has associated current ICD–10 codes that have demonstrated pricing stability.

We further propose to codify these criteria for included cancer types at § 512.230(a) of our regulation.

We propose the following criteria for purposes of removing cancer types under the RO Model.

- RT is no longer appropriate to treat a cancer type per nationally recognized, evidence-based clinical treatment guidelines;
- CMS discovers a ≥10 percent (≥10%) error in established national baseline rates; or
- The Secretary determines a cancer type not to be suitable for inclusion in the Model.

We further propose to codify these criteria for removing cancer types at § 512.230(b) of our regulation.

We identified 17 cancer types in Table 1 that meet our proposed criteria. These 17 cancer types are commonly treated with RT and Medicare claims data was sufficiently reliable to calculate prices for prospective episode payments that accurately reflect the average resource utilization for an episode. These cancer types are made up of specific ICD–9 and ICD–10 diagnosis codes. For example, as shown in Table 1, there are cancer types for ''breast cancer'' and ''prostate cancer,'' which are categorical terms that represent a grouping of ICD–9 and ICD–10 codes affiliated with those conditions. To identify these cancer types and their relevant diagnosis codes to include in the Model, we identified cancers that are treated with RT.

Using the list of cancer types and relevant diagnosis codes, we analyzed the interquartile ranges of the episode prices across diagnosis codes within each cancer type to determine pricing stability. We chose to exclude benign neoplasms and those cancers that are rarely treated with radiation because there were not enough episodes for reliable pricing and they were too variable to pool.

During our review of skin cancer episodes, we discovered that Current Procedural Terminology® (CPT®) code 0182T (electronic brachytherapy treatment), which was being used mainly by dermatologists to report treatment for non-melanoma skin cancers, was deleted and replaced with two new codes (CPT® code 0394T to report high dose rate (HDR) electronic skin brachytherapy and 0395T to report HDR electronic interstitial or intracavitary treatments) in 2016. Local coverage determinations (LCDs) that provide information about whether or not a particular item or service is covered were created and subsequently changed during this time period. Our analysis suggested that the volume and pricing of these services dropped significantly between 2015 and 2016, with pricing decreasing more than 50 percent. As a result, we did not believe that we could price episodes for skin cancers that accurately reflect the average resource utilization for an episode. Thus, skin cancer was excluded.

We are proposing that the RO Model's included cancer types would include those that are commonly treated with RT and that can be accurately priced for prospective episode payments. An up-to-date list of cancer types would be kept on the RO Model website.

We propose to define the term ''included cancer types'' to mean the

[29] The current Medicare policy on routine cost in clinical trials is described in Routine Costs in Clinical Trials 100–3 section 310.1.

cancer types determined by the criteria set forth in § 512.230, which are included in the RO Model test.

TABLE 1: IDENTIFIED CANCER TYPES AND CORRESPONDING ICD-9 AND ICD-10 CODES

Cancer Type	ICD-9 Codes	ICD-10 Codes
Anal Cancer	154.2x, 154.3x	C21.xx
Bladder Cancer	188.xx	C67.xx
Bone Metastases	198.5x	C79.5x
Brain Metastases	198.3x	C79.3x
Breast Cancer	174.xx, 175.xx, 233.0x	C50.xx, D05.xx
Cervical Cancer	180.xx	C53.xx
CNS Tumors	191.xx, 192.0x, 192.1x, 192.2x, 192.3x, 192.8x, 192.9x	C70.xx, C71.xx, C72.xx
Colorectal Cancer	153.xx, 154.0x, 154.1x, 154.8x	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	140.xx, 141.0x, 141.1x, 141.2x, 141.3x, 141.4x, 141.5x, 141.6x, 141.8x, 141.9x, 142.0x, 142.1x, 142.2x, 142.8x, 142.9x, 143.xx, 144.xx, 145.0x, 145.1x, 145.2x, 145.3x, 145.4x, 145.5x, 145.6x, 145.8x, 145.9x, 146.0x, 146.1x, 146.2x, 146.3x, 146.4x, 146.5x, 146.6x, 146.7x, 146.8x, 146.9x 147.xx, 148.0x, 148.1x, 148.2x, 148.3x, 148.8x, 148.9x, 149.xx, 160.0x, 160.1x, 160.2x, 160.3x, 160.4x, 160.5x, 160.8x, 160.9x, 161.xx, 195.0x	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Kidney Cancer	189.0x	C64.xx
Liver Cancer	155.xx, 156.0x, 156.1x, 156.2x, 156.8x, 156.9x	C22.xx, C23.xx, C24.xx
Lung Cancer	162.0x, 162.2x, 162.3x, 162.4x, 162.5x, 162.8x, 162.9x, 165.xx	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	202.80, 202.81, 202.82, 202.83, 202.84, 202.85, 202.86, 202.87, 202.88, 203.80, 203.82, 200.0x, 200.1x, 200.2x, 200.3x, 200.4x, 200.5x, 200.6x, 200.7x, 200.8x, 201.xx, 202.0x, 202.1x, 202.2x, 202.4x, 202.7x, 273.3x	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x
Pancreatic Cancer	157.xx	C25.xx
Prostate Cancer	185.xx	C61.xx
Upper GI Cancer	150.xx, 151.xx, 152.xx	C15.xx, C16.xx, C17.xx
Uterine Cancer	179.xx, 182.xx	C54.xx, C55.xx

We would maintain the list of ICD–10 codes for included cancer types under the RO Model on the RO Model website. Any addition or removal of these proposed cancer types would be communicated via the RO Model website and written correspondence to RO participants. We would notify RO participants of any changes to the diagnosis codes for the included cancer types per the CMS standard process for announcing coding changes and update the list on the RO Model website no later than 30 days prior to each PY.

We invite public comments on our proposal.

b. Episode Length and Trigger

(1) Proposed Episode Length

We are proposing that the length of an episode under the RO Model be 90 days. Based on the analysis of Medicare claims data between January 1, 2014 and December 30, 2015, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. Day 1 would be the date of service that a Professional participant or Dual participant furnishes the initial treatment planning service (included in the PC), provided that a Technical participant or Dual participant furnishes an RT delivery service (included in the TC) within 28 days of the treatment planning service. In other words, the relevant 90-day period would be considered an episode only if a Technical participant or Dual participant furnishes the TC to an RO beneficiary within 28 days of when a Professional participant or Dual participant furnishes the PC to such RO beneficiary. When those circumstances

occur, the ''start'' of the episode would be the date of service that the initial treatment planning service was rendered. If, however, a Technical participant or Dual participant does not furnish the TC to an RO beneficiary within the 28-day period, then no episode will have occurred and any payment would be made to the RO participant in accordance with our incomplete episode policy. We refer readers to sections III.C.5.b and III.C.6.a for an overview of our proposed episode trigger and incomplete episode policies, respectively.

To better understand the standard length of a course of RT, we analyzed Medicare claims for beneficiaries who received any RT services between January 1, 2014 and December 30, 2015. Preliminary analysis showed that average Medicare spending for radiation treatment tends to drop significantly 9 to 11 weeks following the initial RT service for most diagnoses, including prostate, breast, lung, and head and neck cancers. Furthermore, based on this data, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. We intend to make a summary-level, de-identified file titled the ''RT Expenditures by Time'' available on the RO Model's website that supports our findings in this preliminary analysis.

Based on our analysis, for the purpose of establishing the national base rates for the PC and TC of each episode for each cancer type, episodes were triggered by the occurrence of a treatment planning service followed by a radiation treatment delivery service within 28 days of the treatment planning service (HCPCS codes 77261–77263). In addition, for the purpose of establishing the national base rates in section III.C.6.c, the episodes lasted for 89 days starting from the day after the initial treatment planning service in order to create a full 90-day episode.

Based on these analyses, we are proposing a 90 day episode duration.

(2) Proposed Episode Trigger

Because we only want to include episodes in which beneficiaries actually receive RT services, we propose that an episode would be triggered only if both of the following conditions are met: (1) There is an initial treatment planning service (that is, submission of treatment planning HCPCS codes 77261–77263, all of which would be included in the PC) furnished by a Professional participant or a Dual participant; and (2) at least one radiation treatment delivery service (as listed in Table 2: List of RO Model Bundled HCPCS) is furnished by a Technical participant or a Dual participant within the following 28 days. The PC is attributed to the RT supplier of the initial radiation treatment planning service. The TC is attributed to the RT provider or RT supplier of the initial radiation treatment delivery service. As we previously explained, an episode that is triggered would end 89 days after the date of the initial treatment planning service, creating a 90 day episode. If, however, a beneficiary receives an initial treatment planning service but does not receive RT treatment from a Technical participant or Dual participant within 28 days, then the requirements for triggering an episode would not be met, and no RO episode will have occurred, and the proposed incomplete episode policy would take effect.

In those cases where the TC of an episode is not furnished by a Dual participant (that is, when the same RO participant does not furnish both the PC and the TC of an episode), the Professional participant would provide the Technical participant with a signed radiation prescription and the final treatment plan, all of which is usually done electronically. This will inform the Technical participant of when the episode began.

(3) Proposed Policy for Multiple Episodes and the Clean Period

Given our findings that 99 percent of Medicare FFS beneficiaries complete treatment within 90 days of the initial treatment planning service, and to minimize any potential incentive for a RO participant to extend a treatment course beyond the 90-day episode in order to trigger a new episode, we propose that another episode may not be triggered until at least 28 days after the previous episode has ended. This is because, while a missed week of treatment is not uncommon, a break from RT services for more four weeks (or 28 days) generally signals the start of a new course of treatment.[30] We refer to the 28-day period after an episode has ended, during which time a RO participant would bill for medically necessary RT services furnished to a RO beneficiary in accordance with Medicare FFS billing rules, as the ''clean period.'' We propose to codify the term ''clean period'' at § 512.205 of our regulations.

If clinically appropriate, a RO participant may initiate another episode for the same beneficiary after the 28-day clean period has ended. During the clean period, a RO participant would be required to bill for RT services for the beneficiary in accordance with FFS billing rules. The Innovation Center would monitor the extent to which services are furnished outside of 90-day episodes, including during clean periods, and for the number of RO beneficiaries who receive RT in multiple episodes.

We invite public comment on our proposal.

c. Proposed Included RT Services

We propose that the RO Model would include most RT services furnished in HOPDs and freestanding radiation therapy centers. Services furnished within an episode of RT usually follow a standard, clearly defined process of care and generally include a treatment consultation, treatment planning, technical preparation and special services (simulation), treatment delivery, and treatment management, which are also categorical terms used to generally describe RT services. The subcomponents of RT services have been described in the following manner:[31]

Consultation: A consultation is an evaluation and management (E&M) service, which typically consists of a medical exam, obtaining a problem-focused medical history, and decision making about the patient's condition/care.

Treatment planning: Treatment planning tasks include determining a patient's disease-bearing areas, identifying the type and method of radiation treatment delivery, specifying areas to be treated, and selecting radiation therapy treatment techniques. Treatment planning often includes simulation (the process of defining relevant normal and abnormal target anatomy and obtaining the images and data needed to develop the optimal radiation treatment process). Treatment planning may involve marking the area to be treated on the patient's skin, aligning the patient with localization lasers, and/or designing immobilization devices for precise patient positioning.

Technical preparation and special services: Technical preparation and special services include radiation dose planning, medical radiation physics, dosimetry, treatment devices, and special services. More specifically, these services also involve building treatment devices to refine treatment delivery and mathematically determining the dose

[30] CMS was advised by radiation oncologists consulting on the design of the Model that four weeks signals the start of a new course of treatment.

[31] American Society for Radiation Oncology (ASTRO). Basics of RO Coding. *https://www.astro.org/Basics-of-Coding.aspx.*

and duration of radiation therapy. Radiation oncologists frequently work with dosimetrists and medical physicists to perform these services.

Radiation treatment delivery services: Radiation treatment is usually furnished via a form of external beam radiation therapy or brachytherapy, and includes multiple modalities. Although treatment generally occurs daily, the care team and patient determine the specific timing and amount of treatment. The treating physician must verify and document the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.

Treatment management: Radiation treatment management typically includes review of port films, review and changes to dosimetry, dose delivery, treatment parameters, review of patient's setup, patient examination, and follow-up care.

Our claims analysis revealed that beneficiaries received a varying number of consultations from different physicians prior to the treatment planning visit, which determines the prescribed course of radiation therapy, including modality and number of treatments to be delivered. We are proposing to include treatment planning, technical preparation and special services, treatment delivery, and treatment management as the RT services in an episode paid for by CMS, and we propose to codify this at § 512.235. E&M services are furnished by a wide range of physician specialists (for example, primary care, general oncology, others) whereas the other radiation services are typically only furnished by radiation oncologists and their team. This is reflected in the HCPCS code set used to bill for these services. In our review of claims data, many different types of specialists furnish E&M services. It is common for multiple entities to bill for treatment consultations (E&M services) for the same beneficiary, whereas typically only a single entity bills for RT services for a beneficiary when we limited the services considered to treatment planning, technical preparation and special services, treatment delivery, and treatment management. When consultations and visits were included for an analysis of professional RT services during 2014–2016, only 18 percent of episodes involved billing by a single entity (TIN or CCN) as opposed to 94 percent of episodes when consultations and visits were excluded. When consultations and visits were included for an analysis of technical RT services during 2014–2016, 78 percent of episodes involved billing by a single entity (TIN or CCN) as opposed to 94 percent of episodes when consultations and visits were excluded. The difference in percentages is due to the fact that patients see a wide variety of doctors during the course of cancer treatment, which will often involve visits and consultations.

We are not proposing to include E&M services as part of the episode payment. RO participants would continue to bill E&M services under Medicare FFS.

We would also exclude low volume RT services from the RO Model. These include certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. We are excluding these services from the Model because they are not offered in sufficient amounts for purposes of evaluation.

Given that physicians sometimes contract with others to supply and administer brachytherapy radioactive sources (or radioisotopes), we considered omitting these services from the episode payment. After considering either including or excluding brachytherapy radioelements from the RO Model, we are proposing to include brachytherapy radioactive elements, rather than omit these services, from the episodes because they are generally furnished in HOPDs and the hospitals are usually the purchasers of the brachytherapy radioactive elements. When not furnished in HOPDs, these services are furnished in ASCs, which we are proposing to exclude from the Model. We invite public comments on our proposal, including comments on the proposed inclusion of brachytherapy radioactive sources in the episodes.

The RO Model payments would replace current FFS payments only for the included RT services furnished during an episode. For the included modalities, proposed in section III.C.5.d of this proposed rule, the RO Model episode would include HCPCS codes related to radiation oncology treatment. Please see section III.C.7 for our proposed billing guidelines. We have compiled a list of HCPCS codes that represent treatment planning, technical preparation and special services, treatment delivery, and treatment management for the included modalities. RT services included on this list are referred to as ''RO Model Bundled HCPCS'' when they are provided during a RO Model episode since payment for these services is bundled into the RO episode payment. Thus, we propose to codify at § 512.270 that these RT services would not be paid separately during an episode. We may add, remove, or revise any of the bundled HCPCS codes included in the RO Model. We would notify participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file. We would maintain a list of the HCPCS codes included in the RO Model on the RO Model website.

BILLING CODE P

TABLE 2: LIST OF RO MODEL BUNDLED HCPCS

HCPCS	HCPCS Description	Category
55920	Placement Pelvic Needles/Catheters, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57155	Placement Tandem and Opioids, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57156	Placement Vaginal Cylinder, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
58346	Placement Heyman Capsules, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placement	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Telethx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Telethx isodose plan cplx	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77316	Brachytx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77317	Brachytx isodose intermed	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77318	Brachytx isodose complex	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77321	Special teletx port plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77331	Special radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77332	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery
77387	Guidance for radiaj tx dlvr	Radiation Treatment Delivery (Guidance)
77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77424	Io rad tx delivery by x-ray	Radiation Treatment Delivery
77425	Io rad tx deliver by elctrns	Radiation Treatment Delivery
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery
77522	Proton trmt simple w/comp	Radiation Treatment Delivery
77523	Proton trmt intermediate	Radiation Treatment Delivery
77525	Proton treatment complex	Radiation Treatment Delivery
77761	Apply intrcav radiat simple	Radiation Treatment Delivery
77762	Apply intrcav radiat interm	Radiation Treatment Delivery
77763	Apply intrcav radiat compl	Radiation Treatment Delivery
77767	Hdr rdncl skn surf brachytx	Radiation Treatment Delivery
77768	Hdr rdncl skn surf brachytx	Radiation Treatment Delivery
77770	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77771	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77772	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77778	Apply interstit radiat compl	Radiation Treatment Delivery
77789	Apply surf ldr radionuclide	Radiation Treatment Delivery

HCPCS	HCPCS Description	Category
77790	Radiation handling	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77799	Radium/radioisotope therapy	Radiation Treatment Delivery
A9527	Iodine i-125 sodium iodide	Radiation Treatment Delivery (Brachytherapy Materials)
C1715	Brachytherapy needle	Radiation Treatment Delivery (Brachytherapy Materials)
C1716	Brachytx, non-str, gold-198	Radiation Treatment Delivery (Brachytherapy Materials)
C1717	Brachytx, non-str,hdr ir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1719	Brachytx, ns, non-hdrir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1728	Catheter, brachytherapy seed administration	Radiation Treatment Delivery (Brachytherapy Materials)
C2616	Brachytx, non-str,yttrium-90	Radiation Treatment Delivery (Brachytherapy Materials)
C2634	Brachytx, non-str, ha, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2635	Brachytx, non-str, ha, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2636	Brachy linear, non-str,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2638	Brachytx, stranded, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2639	Brachytx, non-stranded,i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2640	Brachytx, stranded, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2641	Brachytx, non-stranded,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2642	Brachytx, stranded, c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2643	Brachytx, non-stranded,c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2644	Brachytx cesium-131 chloride	Radiation Treatment Delivery (Brachytherapy Materials)
C2645	Brachytx planar, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2698	Brachytx, stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
C2699	Brachytx, non-stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)
Q3001	Brachytherapy radioelements	Radiation Treatment Delivery (Brachytherapy Materials)
77469	Intraoperative radiation treatment management	Treatment Management

BILLING CODE C

d. Proposed Included Modalities

We propose to include the following RT modalities in the Model: Various types of external beam RT, including 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy. We are proposing to include all of these modalities because they are the most commonly used to treat the 17 included cancer types and including these modalities would allow us to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.

Because the OPPS and PFS are resource-based payment systems, higher payment rates are typically assigned to services that use more expensive equipment. Additionally, newer treatments have traditionally been assigned higher payment. Researchers have indicated that resource-based payments may encourage health care providers to purchase higher priced equipment and furnish higher-cost services, if they have a sufficient volume of patients to cover their fixed costs.[32] Higher payment rates for services involving certain treatment modalities may encourage use of those modalities over others.[33]

Medicare payment for RT has increased substantially. From 2000 to 2010, for example, the volume of physician billing for radiation treatment increased 8.2 percent, while Medicare Part B spending on RT increased 216 percent.[34] Most of the increase in the 2000 to 2010 time period was due to the adoption and uptake of IMRT. From 2010 to 2016, spending and volume for PBT in FFS Medicare grew rapidly,[35] driven by a sharp increase in the number of proton beam centers and Medicare's relatively broad coverage of this treatment. While we cannot assess through claims data what caused this

[32] Falit, B. P., Chernew, M. E., & Mantz, C.A. (2014). Design and implementation of bundled payment systems for cancer care and RT. International Journal of Radiation Oncology• Biology• Physics, 89(5), 950–953.

[33] Ibid.

[34] Shen, X., Showalter, T. N., Mishra, M.V., Barth, S., Rao, V., Levin, D., & Parker, L. (2014). Radiation oncology services in the modern era: Evolving patterns of usage and payments in the office setting for Medicare patients from 2000 to 2010. Journal of Oncology Practice, 10(4), e201–e207.

[35] Spending in PBT rose from $47 million to $115 million, and the number of treatment sessions for PBT rose from 47,420 to 108,960, during that period.

increase in PBT, we can monitor changes in the utilization of treatment modalities during the course of the Model. The aforementioned increase in PBT volume may depend on a variety of factors.

The RO Model's episode payment is designed, in part, to give RT providers and RT suppliers greater predictability in payment and greater opportunity to clinically manage the episode, rather than being driven by FFS payment incentives. The design of the payment model groups together different modalities for specific cancer types, often with variable costs, into a single payment that reflects average treatment costs. The Model would include an historical experience adjustment which would account for RO participant's historical care patterns, including a RO participant's historical use of more expensive modalities, and certain factors that are beyond a provider's control. We believe that applying the same payment for the most commonly used RT modalities would allow physicians to pick the highest-value modalities.

Given the goals of the RO Model as well as the proposed payment design, we believe it is important to treat all modalities equally.

With respect to PBT, there has been debate regarding the benefits of proton beam relative to other, less expensive modalities. The Institute for Clinical and Economic Review (ICER) evaluated the evidence of the overall net health benefit (which takes into account clinical effectiveness and potential harms) of proton beam therapy in comparison with its major treatment alternatives for various types of cancer.[36] ICER concluded that PBT has superior net health benefit for ocular tumors and incremental net health benefit for adult brain and spinal tumors and pediatric cancers. ICER judged that proton beam therapy is comparable with alternative treatments for prostate, lung, and liver cancer, although the strength of evidence was low for these conditions. In a June 2018 report to Congress, MedPAC discussed Medicare coverage policy and use of low-value care and examined services, including PBT, which lack evidence of comparative clinical effectiveness and are therefore potentially low value.[37] They concluded that there are many policy tools, including new payment models, that CMS could consider adopting to reduce the use of low-value services. Given the continued debate around the benefits of PBT, and understanding that the PBT is more costly, we believe that it would be appropriate to include in the RO Model's test, which is designed to evaluate, in part, site neutral payments for RT services. We invite public comment our proposal to include PBT in the RO Model.

We are considering excluding PBT from the included modalities in instances where a RO beneficiary is participating in a federally-funded, multi-institution, randomized control clinical trial for PBT so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. We invite public comment on whether or not the RO Model should include RO beneficiaries participating in federally-funded, multi-institution, randomized control clinical trials for PBT.

6. Proposed Pricing Methodology

a. Overview

The proposed pricing methodology describes the data and process used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type. We propose to define the term ''participant-specific professional episode payment'' as a payment made by CMS to a Professional participant or Dual participant for the provision of the professional component of RT services furnished to a RO beneficiary during an episode, which is calculated as set forth in proposed § 512.255. We further propose to codify this term, ''participant-specific professional episode payment,'' at § 512.205 of our regulations.

We propose to define the term ''participant-specific technical episode payment'' as a payment made by CMS to a Technical participant or Dual participant for the provision of the technical component of RT services to a RO beneficiary during an episode, which is calculated as set forth in proposed § 512.255. We further propose to codify this term, ''participant-specific technical episode payment,'' at § 512.205 of our regulations.

There are eight primary steps to the proposed pricing methodology. In the first step, we would create a set of national base rates for the PC and TC of the included cancer types, yielding 34 different national base rates. Each of the national base rates represents the historical average cost for an episode of care for each of the included cancer types. The calculation of these rates would be based on Medicare FFS claims paid during the CYs 2015–2017 that are included under an episode where the initial treatment planning service occurred during the CYs 2015–2017 as described in section III.C.6.b. If an episode straddles calendar years, the episode and its claims are counted in the calendar year for which the initial treatment planning service is furnished. We exclude those episodes that do not meet the criteria described in section III.C.5 of this proposed rule. From those episodes, we would then calculate the amount CMS paid on average to providers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model's national base rates. Unless a broad rebasing is done after a later PY in the Model, these national base rates would be fixed throughout the model performance period.

In the second step, we would apply a trend factor to the 34 different national base rates to update those amounts to reflect current trends in payment for RT services and the volume of those services outside of the Model under OPPS and PFS. We propose to define the term ''trend factor'' to mean an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services. We propose to codify the term ''trend factor'' at § 512.205 of our regulations. In this step, we would calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the Model. More specifically, the calculations would update the national base rates using the most recently available claims data of those non-participating providers and suppliers and the volume at which they billed for RT services as well as their corresponding payment rates. Adjusting the national base rates with a trend factor would help ensure payments made under the Model appropriately reflect changes in treatment patterns and payment rates that have occurred under OPPS and PFS.

In the third step, we would adjust the 34 now-trended national base rates to account for each Participant's historical experience and case mix history. The historical experience and case mix adjustments account for providers' historical care patterns and certain factors that are beyond a provider's control, which vary systematically among providers and suppliers so as to

[36] Ollendorf, D.A., J.A. Colby, and S. D. Pearson. 2014. Proton beam therapy. Report prepared by the Institute for Clinical and Economic Review for the Health Technology Assessment Program, Washington State Health Care Authority. Olympia, WA: Washington State Health Care Authority. *https://icer-review.org/wp-content/uploads/2014/07/pbt_final_report_040114.pdf.*

[37] *http://medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf.*

warrant adjustment in payment. There would be one professional and/or one technical case mix adjustment per RO participant depending on the type of component the RO Participant furnished during the 2015–2017 period, just as there would be one professional and/or one technical historical experience adjustment per RO participant, depending on the type of component the RO Participant furnished during the 2015–2017 period. We would generate each RO participant's case mix adjustments using an ordinary least squares (OLS) regression model that predicts payment based on a set of beneficiary characteristics found to be strongly correlated to cost. In contrast, we would generate each RO participant's historical experience adjustments based on Winsorized payment amounts for episodes attributed to the RO participant during the calendar years 2015–2017. The historical experience adjustments for each RO participant would be further weighted by an efficiency factor. The efficiency factor measures if a RO participant's episodes (from the retrospectively constructed episodes from 2015–2017 claims data) have historically been more or less costly than the national base rates, and this determines the weight at which each RO participant's historical experience adjustments are applied to the trended national base rates.

In the fourth step, we would further adjust payment by applying a discount factor. The discount factor, the set percentage by which CMS reduces an episode payment amount, after the trend factor and adjustments have been applied, but before standard CMS adjustments including the geographic practice cost index (GPCI), sequestration, and beneficiary cost-sharing, would reserve savings for Medicare and reduce beneficiary cost-sharing. We propose to codify the term ''discount factor'' at § 512.205.

In the fifth step, we would further adjust payment by applying an incorrect payment withhold, and either a quality withhold or a patient experience withhold, depending on the type of component the RO participant furnished under the Model. The incorrect payment withhold would reserve money for purposes of reconciling duplicate RT services and incomplete episodes during the reconciliation process, which we discuss further in section III.C.11. We propose to define the term ''duplicate RT service'' to mean any included RT service (as identified at § 512.235) that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC of that RO beneficiary after the episode. We propose to codify ''duplicate RT service'' at § 512.205. An incomplete episode means the circumstances in which an episode does not occur because: (1) A Technical participant or a Dual participant does not furnish a technical component to a RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an RT treatment planning service to that RO beneficiary; or (2) traditional Medicare stops being the primary payer at any point during the relevant 90-day period the RO beneficiary; or (3) a RO beneficiary stops meeting the beneficiary population criteria under § 512.215(a) or triggers the beneficiary exclusion criteria under § 512.215(b) before the technical component of an episode initiates.

We would also adjust for a quality withhold for the professional component of the episode. This withhold would allow the Model to include quality measure results as a factor when determining payment to participants under the terms of the APM, which is one of the criteria for an APM to qualify as an Advanced APM as specified in 42 CFR 414.1415(b)(1). We would adjust for a patient experience withhold for the technical component of the episode starting in PY3 to account for patient experience in the Model. We would then apply all of these adjustments, as appropriate to each RO participant's trended national base rates.

In the sixth step, we would apply geographic adjustments to payments. In the seventh and final eighth step, we would apply beneficiary coinsurance and a 2 percent adjustment for sequestration to the trended national base rates that have been adjusted as described in steps three through six, yielding participant-specific payment amounts for the provision of the PC and TC of each included cancer type in the Model. We would calculate a total of 34 participant-specific professional and technical episode payment amounts for Dual participants, whereas we would only calculate 17 participant-specific professional episode payment amounts or 17 participant-specific technical episode payment amounts for Professional participants and Technical participants, since they furnish only the PC or TC, respectively.

Following this description of the data and process used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type is a pricing example for an episode of lung cancer. We provide this example to show how each pricing component (that is, national base rates, trend factors, case mix and historical experience adjustments, withholds, discount factors, geographic adjustment, beneficiary coinsurance, and sequestration) figures into these amounts. We also intend to provide a summary-level, de-identified file titled the ''RO Episode File (2015–2017),'' on the RO Model's website to further facilitate understanding of the RO Model's pricing methodology.

b. Proposal To Construct Episodes Using Medicare FFS Claims and Calculate Episode Payment

We would construct episodes based on dates of service for Medicare FFS claims paid during the CYs 2015–2017 as well as claims that are included under an episode where the initial treatment planning service occurred during the CYs 2015–2017 as described in section III.C.3.d. We would exclude those episodes that do not meet the criteria described in section III.C.5 of this proposed rule. Each episode and its corresponding payment amounts, one for the PC and one for the TC, would represent the sum totals of calculated payment amounts for the professional services and the technical services of the radiation treatment furnished over a defined 90-day period as described in section III.C.5.b. We would calculate the payment amounts for the PC and TC of each episode as the product of: (a) The OPPS or PFS national payment rates for each of the RT services included in the Model multiplied by (b) the volume of each professional or technical RT service included on a paid claim line during each episode. We would neither Winsorize nor cap payment amounts nor adjust for outliers in this step.

So that all payment amounts are in 2017 dollars, we would convert 2015 payment amounts to 2017 by multiplying: (a) The 2015 payment amounts by the ratio of (b) average payment amounts for episodes that initiated in 2017 to (c) average payment amounts for episodes that initiated in 2015. We would apply this same process for episodes starting in 2016. To weigh the most recent observations more heavily than those that occurred in earlier years, we would weight episodes that initiated in 2015 at 20 percent, episodes that initiated in 2016 at 30 percent, and episodes that initiated in 2017 at 50 percent.

Conversion of 2015 and 2016 payment amounts to 2017 dollars would be done differently, depending on which step of the pricing methodology is being calculated. For instance, episode payments for episodes used to calculate national base rates and case mix

regression models would only be furnished in the HOPD setting, and consequently, for purposes of calculating the national base rates and case mix regression models, the conversion of episode payment amounts to 2017 dollars would be based on average payments of episodes from only the HOPD setting. On the other hand, episode payments for episodes used to calculate the historical experience adjustments would be furnished in both the HOPD and freestanding radiation therapy center settings (that is, all episodes nationally), and consequently, for purposes of calculating the historical experience adjustments, the conversion of episode payment amounts to 2017 dollars would be based on average payments of all episodes nationally from both the HOPD and freestanding radiation therapy center settings.

c. Proposed National Base Rates

We propose to define the term ''national base rate'' to mean the total payment amount for the relevant component of each episode before application of the trend factor, discount factor, adjustments, and applicable withholds for each of the proposed included cancer types. We further propose to codify this term at § 512.205 of our regulations.

The following episodes would be excluded from calculations to determine the national base rates:

- Episodes with any services furnished by a CAH;
- Episodes without positive (>$0) total payment amounts for professional services or technical services;
- Episodes assigned a cancer type not identified as cancer types that meet our criteria (see Table 1);
- Episodes that are not assigned a cancer type;
- Episodes with RT services furnished in Maryland, Vermont, or a U.S. Territory;
- Episodes in which a PPS-exempt cancer hospital furnishes the technical component (is the attributed technical provider);
- Episodes in which a Medicare beneficiary does not meet the eligibility criteria proposed in section III.C.4.

We are proposing to exclude episodes without positive (>$0) total payment amounts for professional services or technical services, since we would only use episodes where the RT services were not denied and Medicare made payment for those RT services. We are proposing to exclude episodes that are not assigned a cancer type and episodes assigned a cancer type not on the list of Included Cancer Types, since the RO Model evaluates the furnishing of RT services to beneficiaries who have been diagnosed with one of the included cancer types. The remaining proposals listed in this section exclude episodes that are in accordance with proposals set forth in section III.C.5.

(1) Proposed National Base Rate Calculation Methodology

When calculating the national base rates, we would only use episodes that meet the following criteria: (1) Episodes initiated in 2015–2017; (2) episodes attributed to a HOPD; and (3) during an episode, the majority of technical services were provided in a HOPD (that is, more technical services were provided in a HOPD than in a freestanding radiation therapy center). OPPS payments have been more stable over time and have a stronger empirical foundation than those under the PFS. The OPPS coding and payments for radiation oncology have varied less year over year than those in the PFS for the applicable time period. In addition, generally speaking, the OPPS payment amounts are derived from information from hospital cost reports, which are based on a stronger empirical foundation that the PFS payment amounts for services involving capital equipment.

CMS would publish the national base rates and provide each RO participant its participant-specific professional episode payment and/or its participant-specific technical episode payment for each cancer type no later than 30 days before the start of the PY in which payments in such amounts would be made.

Our proposed national base rates for the model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3.

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TABLE 3 –NATIONAL BASE RATES BY CANCER TYPE (in 2017 DOLLARS)

RO Model-Specific Placeholder Codes[38]	Professional or Technical	Cancer Type	Base Rate
MXXXX	Professional	Anal Cancer	$2,968
MXXXX	Technical	Anal Cancer	$16,006
MXXXX	Professional	Bladder Cancer	$2,637
MXXXX	Technical	Bladder Cancer	$12,556
MXXXX	Professional	Bone Metastases	$1,372
MXXXX	Technical	Bone Metastases	$5,568
MXXXX	Professional	Brain Metastases	$1,566
MXXXX	Technical	Brain Metastases	$9,217
MXXXX	Professional	Breast Cancer	$2,074
MXXXX	Technical	Breast Cancer	$9,740
MXXXX	Professional	Cervical Cancer	$3,779
MXXXX	Technical	Cervical Cancer	$16,955
MXXXX	Professional	CNS Tumor	$2,463
MXXXX	Technical	CNS Tumor	$14,193
MXXXX	Professional	Colorectal Cancer	$2,369
MXXXX	Technical	Colorectal Cancer	$11,589
MXXXX	Professional	Head and Neck Cancer	$2,947
MXXXX	Technical	Head and Neck Cancer	$16,708
MXXXX	Professional	Kidney Cancer	$1,550
MXXXX	Technical	Kidney Cancer	$7,656
MXXXX	Professional	Liver Cancer	$1,515
MXXXX	Technical	Liver Cancer	$14,650
MXXXX	Professional	Lung Cancer	$2,155
MXXXX	Technical	Lung Cancer	$11,451
MXXXX	Professional	Lymphoma	$1,662
MXXXX	Technical	Lymphoma	$7,444
MXXXX	Professional	Pancreatic Cancer	$2,380
MXXXX	Technical	Pancreatic Cancer	$13,070
MXXXX	Professional	Prostate Cancer	$3,228
MXXXX	Technical	Prostate Cancer	$19,852
MXXXX	Professional	Upper GI Cancer	$2,500
MXXXX	Technical	Upper GI Cancer	$12,619
MXXXX	Professional	Uterine Cancer	$2,376
MXXXX	Technical	Uterine Cancer	$11,221

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d. Proposal To Apply Trend Factors to National Base Rates

We would next apply a trend factor to the 34 different national base rates in Table 3. For each PY, we would calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the Model. We propose that the 34 separate trend factors would be updated and applied to the national base rates prior to the start of each PY (for which they would apply) so as to account for trends in payment rates and volume for RT services outside of the Model under OPPS and PFS.

For the PC of each included cancer type and the TC of each included cancer type, we would calculate a ratio of: (a) Volume-weighted FFS payment rates for

[38] The final HCPCS codes specific to the RO Model would be published in the CY2020 Level 2 HCPCS code file.

RT services included in that component for that cancer type in the upcoming PY (that is, numerator) to (b) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the most recent baseline year (that is, the denominator), which would be FFS rates from 2017.

To calculate the numerator, we would multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor would be applied) was furnished for the most recent calendar year with complete data [39] by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming performance year.

To calculate the denominator, we would multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor would be applying) was furnished in 2017, the most recent year used to calculate the national base rates by (b) the corresponding FFS payment rate in 2017. The volume of HCPCS codes determining the numerator and denominator would be derived from non-participant episodes that would be otherwise eligible for Model pricing. For example, for PY1, we would calculate the trend factor as:

2020 Trend factor = (2017 volume * 2020 corresponding FFS rates as paid under OPPS or PFS)/(2017 volume * 2017 corresponding FFS rates as paid under OPPS or PFS)

We would then multiply: (a) The trend factor for each national base rate by (b) the corresponding national base rate for the PC and TC of each cancer type from Step 1, yielding 34 trended national base rates. The trended national base rates for 2020 would be made available on the RO Model's website once CMS issues the CY 2020 OPPS and PFS final rules that establish payment rates for the year.

To the extent that CMS introduces new HCPCS codes that CMS determines should be included in the Model, we propose to cross-walk the volume based on the existing set of codes to any new set of codes as we do in the PFS rate-setting process.[40]

[39] For 2020 (PY1), the most recent year with complete episode data would be 2017; for 2021 (PY2), the most recent year with complete episode data would be 2018.

[40] The process of cross-walking the volume from a previous set of codes to the new set of codes in rate-setting for the PFS was most recently explained in the CY 2013 PFS Final Rule, 77 FR 68891, 68996–68997.

We propose to use this trend factor methodology as part of the RO Model's pricing methodology.

e. Proposal To Adjust for Case Mix and Historical Experience

After applying the proposed trend factor in section III.C.6.d, we propose to adjust the 34 trended national base rates to account for each RO participant's historical experience and case mix history.

(1) Proposed Case Mix Adjustments

The cost of care can vary according to many factors that are beyond a provider's control, and the presence of certain factors, otherwise referred to here as case mix variables, may vary systematically among providers and warrant adjustment in payment. For this reason, we propose to apply a RO participant-specific case mix adjustment for the PC and the TC that would be applied to the trended national base rates.

We consulted clinical experts in radiation oncology concerning potential case mix variables believed to be predictive of cost. We then tested and evaluated these potential case mix variables and found several variables (cancer type; age; sex; presence of a major procedure; death during the first 30 days, second 30 days, or last 30 days of the episode; and presence of chemotherapy) to be strongly and reliably predictive of cost under the FFS payment system.

Based on the results of this testing, we propose to develop a case mix adjustment, measuring the occurrence of the case mix variables among the beneficiary population that each RO participant has treated historically (that is, among beneficiaries whose episodes have been attributed to the RO participant during 2015–2017) compared to the occurrence of these variables in the national beneficiary profile. The national beneficiary profile is developed from the same episodes used to determine the Model's national base rates, that is 2015–2017 episodes attributed to all HOPDs nationally. We would first Winsorize, or cap, the episode payments in the national beneficiary profile at the 99th and 1st percentiles, with the percentiles being identified separately by cancer type. We would use OLS regression models, one for the PC and one for the TC, to identify the relationship between episode payments and the case mix variables. The regression models would measure how much of the variation in episode payments can be attributed to variation in the case mix variables.

The regression models generate coefficients, which are values that describe how change in episode payment corresponds to the unit change of the case mix variables. From the coefficients, we would determine a RO participant's predicted payments, or the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. For PY1, these predicted payments would be based on episode data from 2015 to 2017. These predicted payments would be summed across all episodes attributed to the RO participant to determine a single predicted payment for the PC or the TC. This process would be carried out separately for the PC and the TC.

We would then determine a RO participant's expected payments or the payments expected when a participant's case mix (other than cancer type) is not considered in the calculation. To do this, we would use the average Winsorized episode payment made for each cancer type in the national beneficiary profile. These average Winsorized episode payments by cancer type would be applied to all episodes attributed to the RO participant to determine the expected payments. These expected payments would be summed across all episodes attributed to a RO participant to determine a single expected payment for the PC or the TC. The difference between a RO participant's predicted payment and a RO participant's expected payment, divided by the expected payment, would constitute either the PC or the TC case mix adjustment for that RO participant. Mathematically this would be expressed as follows:

Case mix adjustment = (Predicted payment − Expected payment)/ Expected payment

Neither the national beneficiary profile nor the regression model's coefficients would change over the course of the Model's performance period. The coefficients would be applied to a rolling 3-year set of episodes attributed to the RO participant so that a RO participant's case mix adjustments take into account more recent changes in the case mix of their beneficiary population. For example, we would use data from 2015–2017 for PY1, data from 2016–2018 for PY2, data from 2017–2019 for PY3, etc.

(2) Proposed Historical Experience Adjustments and Efficiency Factor

To determine historical experience adjustments for a RO participant we would use episodes attributed to the RO

participant that initiated during 2015–2017. We would calculate a historical experience adjustment for the PC (that is, a professional historical experience adjustment) and the TC (that is, a technical historical experience adjustment) based on attributed episodes. For purposes of determining historical experience adjustments, we would use episodes as described in section III.C.6.b (that is, all episodes nationally), except we would Winsorize, or cap, episode payments attributed to the RO participant at the 99th and 1st percentiles. These Winsorization thresholds would be the same Winsorization thresholds used in the case mix adjustment calculation. We would then sum these payments separately for the PC and TC. As with the case mix adjustments, the historical experience adjustments would not vary by cancer type.

The historical experience adjustment for the PC would be calculated as the difference between: The sum of (a) Winsorized payments for episodes attributed to the RO participant during 2015–2017 and (b) the summed predicted payments from the case mix adjustment calculation, which would then be divided by (c) the summed expected payments used in the case mix adjustment calculations. We would repeat these same calculations for the historical experience adjustment for the TC. Mathematically, for episodes attributed to the RO participant, this would be expressed as:

Historical experience adjustment = (Winsorized payments − Predicted payments)/Expected payments

Based on our proposed calculation, if a RO participant's Winsorized episode payments (determined from the retrospectively constructed episodes from 2015–2017 claims data) are equal to or less than the predicted payments used to determine the case mix adjustments, then it would have historical experience adjustments with a value equal to or less than 0.0, and be categorized as historically efficient compared to the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. Conversely, if a RO participant's episode payments are greater than the predicted payments used to determine the case mix adjustments, then it would have historical experience adjustments with a value greater than 0.0 and be categorized as historically inefficient compared to the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. The historical experience adjustments would be weighted differently and therefore, applied to payment (that is the trended national base rates after the participant-specific case mix adjustments have been applied) differently, depending on these categories. To do this, we would use an efficiency factor. Efficiency factor means the weight that a RO participant's historical experience adjustments are given over the course of the Model's performance period, depending on whether the RO participant's historical experience adjustments fall into the historically efficient or historically inefficient category.

For RO participants with historical experience adjustments with a value greater than 0.0, the efficiency factor would decrease over time to reduce the impact of historical practice patterns on payment over the Model's performance period. More specifically, for RO participants with a PC or TC historical experience adjustment with a value greater than 0.0, the efficiency factor would be 0.90 in PY1, 0.85 in PY2, 0.80 in PY3, 0.75 in PY4 and 0.70 in PY5. For those RO participants with a PC or TC historical experience adjustment with a value equal to or less than 0.0, the efficiency factor would be fixed at 0.90 over the Model's performance period.

(3) Proposal To Apply the Adjustments

To apply the case mix adjustment, the historical experience adjustment, and the efficiency factor as described in section III.C.6.e to the trended national base rates detailed in Step 2, for the PC we would multiply: (a) The corresponding historical experience adjustment by (b) the corresponding efficiency factor, and then add (c) the corresponding case mix adjustment and (d) the value of one. This formula creates a combined adjustment that can be multiplied with the national base rates. Mathematically this would be expressed as:

Combined Adjustment = (Historical experience adjustment * Efficiency factor) + Case mix adjustment + 1.0

The combined adjustment would then be multiplied by the corresponding trended national base rate from Step 2 for each cancer type. We would repeat these calculations for the corresponding case mix adjustment, historical experience adjustment, and efficiency factor for the TC, yielding a total of 34 RO participant-specific episode payments for Dual participants and a total of 17 RO participant-specific episode payments for Professional participants and Technical participants.

We propose to use these case mix adjustments, historical experience adjustments, and efficiency factors to calculate the adjustments under the RO Model's pricing methodology.

(4) Proposal for HOPD or Freestanding Radiation Therapy Center With Fewer Than Sixty Episodes During 2015–2017 Period

Under this proposed rule, if a HOPD or freestanding radiation therapy center (identified by a CCN or TIN) furnishes RT services during the model performance period within a selected CBSA and is required to participate in the Model because it meets eligibility requirements, but has fewer than 60 episodes attributed to it during the 2015–2017 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts would equal the trended national base rates in PY1. In PY2, if an RO participant with fewer than 60 episodes attributed to it during the 2015–2017 period continues to have fewer than sixty episodes attributed to it during the 2016–2018 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts would continue to equal the trended national base rates in PY2. However, if the RO participant had 60 or more attributed episodes during the 2016–2018 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts for PY2 would equal the trended national base rates with the case mix adjustment added. In PY3–PY5, we would reevaluate those same RO participants as we did in PY2 to determine the number of episodes in the rolling three year period used in the case mix adjustment for that performance year (for example, PY3 would be 2017–2019). RO participants that continue to have fewer than 60 attributed episodes in the rolling three year period used in the case mix adjustment for that performance year would continue to have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates, whereas those that have 60 or more attributed episodes would have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates with the case mix adjustment added.

(5) Proposal To Apply Adjustments for HOPD or Freestanding Radiation Therapy Center With a Merger, Acquisition, or Other New Clinical or Business Relationship, With or Without a CCN or TIN Change

We are proposing that a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2024 meets the Model's proposed eligibility requirements discussed in section III.C.3. If the new TIN or CCN begins to furnish RT services within a selected CBSA, then it must participate in the Model. We are proposing this policy in order to prevent HOPDs and freestanding radiation therapy centers from engaging in mergers, acquisitions, or other new clinical or business relationships so as to avoid participating in the Model.

The RO Model requires advanced notification so that the appropriate adjustments are made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. This requirement for the RO Model is the same requirement as proposed at § 512.180(c), except that under the RO Model, RO participants must also provide a notification regarding a new clinical relationship that may or may constitute a change in control. If there is sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN. For our proposed policy regarding change in legal business name and change in control provisions, we refer readers to discussion in section II.L and proposed regulations at § 512.180(b) and (c).

f. Proposal To Apply a Discount Factor

After applying participant-specific adjustments under section III.C.6.e to the trended national base rates, we would next deduct a percentage discount from those amounts for each performance year. The discount factor would not vary by cancer type. The discount factor for the PC would be 4 percent. The discount factor for the TC would be 5 percent. We are proposing the 4 and 5 percent discounts based on discounts in other models tested under section 1115A and private payer models. We believe these figures for the discount factor, four and 5 percent for the PC and TC, respectively, strike an appropriate balance in creating savings for Medicare while not creating substantial financial burden on RO participants with respect to reduction in payment.

We propose to apply these discount factors to the RO participant-adjusted and trended payment amounts for each of the RO Model's performance years.

g. Proposal To Apply Withholds

We propose to withhold a percentage of the total episode payments, that is the payment amounts after the trend factor, adjustments, and discount factor have been applied to the national base rates, to address payment issues and to create incentives for furnishing high quality, patient-centered care. We outline our proposals for three withhold policies in this section of this proposed rule.

(1) Proposed Incorrect Payment Withhold

We propose to withhold 2 percent of the total episode payments for both the PC and TC of each cancer type. This 2 percent would reserve money to address overpayments that may result from two situations: (1) Duplicate RT services as described in section III.C.6.a; and (2) incomplete episodes as described in section III.C.6.a of this proposed rule.

We are proposing a withhold for these two circumstances in order to decrease the likelihood of CMS needing to recoup payment, which could cause administrative burden on CMS and potentially disrupt a RO participant's cash flow. We believe that a 2 percent incorrect payment withhold would set aside sufficient funds to capture a RO participant's duplicate RT services and incomplete episodes during the reconciliation process. We anticipate that duplicate RT services requiring reconciliation will be uncommon, and that few overpayments for such services would therefore be subject to our proposed reconciliation process. Claims data from January 1, 2014 through December 31, 2016 show less than 6 percent of episodes had more than one unique TIN or CCN billing for either professional RT services or technical RT services within a single episode. Similarly, our analysis showed that it is uncommon that a RT provider or RT supplier does not furnish a technical component RT service to a beneficiary within 28 days of when a radiation oncologist furnishes an RT treatment planning service to such RO beneficiary.

We would use the annual reconciliation process described in section III.C.11 to determine whether a RO participant is eligible to receive back the full 2 percent withhold amount, a portion of it, or must repay funds to CMS. We propose to define the term ''repayment amount'' to mean the amount owed by a RO participant to CMS, as reflected on a reconciliation report. We propose to codify the term ''repayment amount'' at § 512.205 of our regulations. In addition, we propose to define the term ''reconciliation report'' to mean the annual report issued by CMS to a RO participant for each performance year, which specifies the RO participant's reconciliation payment amount or repayment amount. We further propose to codify the term ''reconciliation report'' at § 512.205.

(2) Proposed Quality Withhold

We propose to also apply a 2 percent quality withhold for the PC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied. This would allow the Model to include quality measure results as a factor when determining payment to participants under the terms of the APM, which is one of the Advanced APM criteria as codified in 42 CFR 414.1415(b)(1). Professional participants and Dual participants would be able to earn back up to the 2 percent withhold amount each performance year based on their aggregate quality score (AQS). We propose to define the term ''AQS'' to mean the numeric score calculated for each RO participant based on its performance on, and reporting of, proposed quality measures and clinical data, as described in section III.C.8.f, which is used to determine the amount of a RO participant's quality reconciliation payment amount. We further propose to codify this term at § 512.205 of our regulations. The annual reconciliation process described in section III.C.11 would determine how much of the 2 percent withhold a Professional participant or Dual participant would receive back.

(3) Proposed Patient Experience Withhold

We would withhold 1 percent for the TC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied starting in PY3 (January 1, 2022 through December 31, 2022) to account for patient experience in the Model. Technical participants and Dual participants would be able to earn back up to the full amount of the patient experience withhold for a given PY based on their results from the patient-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS® Cancer Care Survey) Cancer Care Survey for Radiation Therapy as described in section III.C.8.b. of this proposed rule.

Like the incorrect payment and quality withholds, the annual reconciliation process described in section III.C.11. of this proposed rule would determine how much of the 1 percent withhold a participant would receive back.

We propose the incorrect payment withhold, the quality withhold, and the patient experience withhold be included in the RO Model's pricing methodology.

h. Proposal To Adjust for Geography

Geographic adjustments are standard Medicare adjustments that occur in the claims system. Even though the Model would establish a common payment amount for the same RT services regardless of where they are furnished, payment would still be processed through the current claims systems, with adjustments as discussed in section III.C.7, for OPPS and PFS. Geographic adjustments would be calculated within those shared systems after CMS submits RO Model payment files to the Medicare Administrative Contractors that contain RO participant specific calculations of payment from steps (a) through (g). We would adjust the trended national base rates that have been adjusted for each RO participant's case mix, historical experience and after which the discount rate and withholds have been applied, for local cost and wage indices based on where RT services are furnished, pursuant to existing geographic adjustment processes in the OPPS and PFS.

OPPS automatically applies a wage index adjustment based on the current year post-reclassification hospital wage index to 60 percent (the labor-related share) of the OPPS payment rate. No additional changes to the OPPS Pricer are needed to ensure geographic adjustment.

The PFS geographic adjustment has three components that are applied separately to the three RVU components that underlie the PFS—Work, PE and MP. To calculate a locality-adjusted payment rate for the RO participants paid under PFS, we would create a set of RO Model-specific RVUs using the national (unadjusted) payment rates for each HCPCS code of the included RT services for each cancer type included in the RO Model. First, the trended national base rates for the PC and TC would be divided by the PFS conversion factor (CF) for the upcoming year to create a RO Model-specific RVU value for the PC and TC payment amounts. Next, since the PFS geographic adjustments are applied separately to the three RVU components (Work, PE, and MP), these RO Model-specific RVUs would be split into RO Model-specific Work, PE, and MP RVUs. The 2015–2017 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD would be used to calculate the implied RVU shares, or the proportional weights of each of the three components (Work, PE, and MP) that make up the value of the RO Model-specific RVUs. Existing radiation oncology HCPCS codes that are included in the bundled RO Model codes but paid only through the OPPS would not be included in the calculation. The RVU shares would be calculated as the volume-weighted Work, PE, and MP shares of each included existing HCPCS code's total RVUs in the PFS. The PCs and TCs for the episodes under the Model would have different RO Model-specific RVU shares, but these shares would not vary by cancer type. Table 4 provides the proposed relative weight of each for the PCs and TCs of the RO Model-specific RVUs share.

TABLE 4—RVU SHARES

Professional component			Technical component		
Work	PE	MP	Work	PE	MP
0.66	0.30	0.04	0.00	0.99	0.01

We would include these RO Model-specific RVUs in the same process that calculates geographically adjusted payment amounts for other HCPCS codes under the PFS with Work, PE, and MP and their respective RVU value applied to each RO Model HCPCS code.

We propose to apply the OPPS Pricer as is automatically applied under OPPS outside of the Model. We propose to use RO Model-specific RVU shares to apply PFS RVU components (Work, PE, and MP) to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services.

i. Proposal To Apply Coinsurance

We propose to calculate the coinsurance amount for a RO beneficiary after applying, as appropriate, the proposed case mix and historical experience adjustments, withholds, discount factors, and geographic adjustments to the trended national base rates for the cancer type billed by the RO participant for the RO beneficiary's treatment. Under current policy, Medicare FFS beneficiaries are generally required to pay 20 percent of the allowed charge for services furnished by HOPDs and physicians (for example, those services paid for under the OPPS and PFS, respectively). This policy would remain the same under the RO Model. RO beneficiaries would pay 20 percent of each of the bundled PC and TC payments for their cancer type, regardless of what their total coinsurance payment amount would have been under the FFS payment system.

We believe that maintaining the 20 percent coinsurance payment will help preserve the integrity of the Model test and the goals guiding its policies. Adopting an alternative coinsurance policy that would maintain the coinsurance that would apply in the absence in the Model, where volume and modality type would dictate coinsurance amounts, would change the overall payment that RO participants would receive. This would skew Model results as it would preserve the incentive to use more fractions and certain modality types so that a higher payment amount could be achieved.

We note that, depending on the choice of modality and number of fractions administered by the RO participant during the course of treatment, the coinsurance payment amount of the bundled rate may occasionally be higher than what a beneficiary or secondary insurer would otherwise pay under Medicare FFS. However, because the PC and TC would be subject to withholds and discounts described in the previous section, we believe that, on average, the total coinsurance paid by RO beneficiaries would be lower than what they would have paid under Medicare FFS for all of the services included in an episode. In other words, the proposed withhold and discount factors would, on average, be expected to reduce the total amount RO beneficiaries or secondary insurers would owe RO participants. In addition, because episode payment amounts under the RO Model would include payments for RT services that would likely be provided over multiple visits, the beneficiary coinsurance payment for each of the episode's payment amounts would likewise be higher than it would otherwise be for a single RT service visit. For RO beneficiaries who do not have a secondary insurer, we would encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments via a payment plan (provided the RO participants would inform patients of the installment plan's availability only during the course of the actual billing process).

In addition, we would continue to apply the limit on beneficiary liability for copayment for a procedure (as described in in section 1833(t)(8)(C)(i) of the Act) to the trended national base rates that concern the TC after the case

mix and historical experience adjustments, discount factor, applicable withholds, and geographic adjustment have been applied.

We invite public comment on our proposal to apply the standard coinsurance of 20 percent to the trended national base rates for the cancer type billed by the RO participant for the RO beneficiary's treatment after the proposed case mix and historical experience adjustments, withholds, discount factors, and geographic adjustments have been applied.

j. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

Table 5 details the participant-specific professional episode payment paid by CMS to a single TIN for the furnishing of RT professional services to RO beneficiary for an episode of lung cancer. The participant-specific professional episode payment in this example does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money is needed beyond the withhold amount from the RO participant.

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TABLE 5 EXAMPLE: PARTICIPANT-SPECIFIC PROFESSIONAL EPISODE PAYMENT FOR LUNG CANCER
ALL NUMBERS ARE ILLUSTRATIVE ONLY

	Professional Component	
	Amount	**Formula**
National Base Rate (a)	$2,155.00	
Trend Factor (b)	1.04	
Subtotal (c)	$2,241.20	c = a * b
Case Mix Adjustment (d)	0.02	For example (102-100) / 100
Historical Experience Adjuster (e)	0.14	For example (116-102) / 100
Year 1 Efficiency Factor (f)	0.90	
Adjustments combined (g)	1.15	g = d + (e * f) + 1
Subtotal (h)	$2,568.42	h = c * g
Discount Factor (i)	0.96	
Subtotal (j)	$2,465.68	j = i * h
Withhold #1 (Incorrect Payment) (k)	0.98	
Withhold #2 (Quality Performance) (l)	0.98	
Subtotal2 (m)	$2,368.04	m = j * k * l
Geographic Adjustment (n)	1.02	
2019 Total Episode Payment to Participant including Coinsurance owed by RO beneficiary (o)	$2,415.40	o = m * n
20% Beneficiary Coinsurance Determined (p)	**$483.08**	**p = o * 0.20**
80% Participant Payment (q)	$1,932.32	q = o * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (r) [r = participant-specific professional episode payment]	$1,893.67	r = q * 0.98
Episode Payment 1 (s)*	**$946.84**	**s = r / 2**
Episode Payment 2 (t)*	**$946.84**	**t = r / 2**

^ .All numbers are rounded to two decimal places.

Table 6 details the participant-specific technical episode payment paid by CMS to a single TIN or single CCN for the furnishing of RT technical services to a RO beneficiary for an episode of lung cancer. The sequence and naming conventions of steps (n)–(r) in Table 6 may vary under the OPPS.

TABLE 6 EXAMPLE: PARTICIPANT-SPECIFIC TECHNICAL EPISODE PAYMENT FOR LUNG CANCER IN PY1 AND PY2

ALL NUMBERS ARE ILLUSTRATIVE ONLY^

	Technical Component	
	Amount	**Formula**
National Base Rate (a)	$11,451.00	
Trend Factor (b)	1.04	
Subtotal (c)	$11,909.04	c = a * b
Case Mix Adjustment (d)	0.02	For example (102-100) / 100
Historical Experience Adjustment (e)	0.11	For example (113-102) / 100
Year 1 Efficiency Factor (f)	0.90	
Adjustments combined (g)	1.12	g = d + (e * f) + 1
Subtotal (h)	$13,326.22	h = c * g
Discount Factor (i)	0.95	
Subtotal (j)	$12,659.91	j = i * h
Withhold #1 (Incorrect Payment) (k)	0.98	
Withhold #2 (Patient Experience) (l) - NOT APPLIED UNTIL PY3		
Subtotal2 (m)	$12,406.71	m = j * k
Geographic Adjustment (n)	1.02	
2019 Total Episode Payment to Participant including coinsurance owed by RO beneficiary (o)	$12,654.84	o = m * n
20% Beneficiary Coinsurance Determined (p)	**$2,530.97**	**p = o * 0.20**
80% Participant Payment (q)	$10,123.87	q = o * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (r) [r = participant-specific technical episode payment]	$9,921.40	r = q * 0.98
Episode Payment 1 (s)*	**$4,960.70**	**s = r / 2**
Episode Payment 2 (t)*	**$4,960.70**	**t = r / 2**

^ All numbers are rounded to two decimal places.

BILLING CODE C

We invite public comment on our proposed pricing methodology.

7. Proposed Professional and Technical Billing and Payment

Similar to how many procedure codes have professional and technical components as identified in the CMS National Physician Fee Schedule Relative Value File, all episodes would be split into two components, the PC and the TC, to allow for use of current claims systems for PFS and OPPS to be used to adjudicate RO Model claims. We believe that the best design for a prospective episode payment system for RT services is to pay the full participant-specific professional and technical episode payment amounts in two installments. We believe that two payments reduce the amount of money that may need to be recouped due to incomplete episodes and reduces the likelihood that the limit on beneficiary liability for copayment for a procedure provided in a HOPD (as described in section 1833(t)(8)(C)(i) of the Act) is met.

Accordingly, we propose to pay for complete episodes in two installments: One tied to when the episode begins, and another tied to when the episode ends. Under this proposed policy a Professional participant would receive two installment payments for furnishing the PC of an episode, a Technical participant would receive two installment payments for furnishing the TC of an episode, and a Dual participant would receive two installment payments for furnishing the PC and TC of an episode.

To reduce burden on RO participants, we propose to make the prospective episode payments for RT services covered under the RO Model using the existing Medicare payment systems by making RO Model-specific revisions to the current Medicare FFS claims processing systems. We would make changes to the current Medicare payment systems using the standard Medicare Fee for Service operations policy related Change Requests (CRs).

Our proposed design for testing a prospective episode payment model (that is, the RO Model) for RT services requires making prospective episode payments for all RT services included in an episode, as proposed in section III.C.5.c, instead of using Medicare FFS payments for services provided during an episode. Local coverage determinations (LCDs), which provide information about the reasonable and necessary conditions of coverage

allowed, would still apply to all RT services provided in an episode.

Professional participants and Dual participants would be required to bill a new model-specific HCPCS code and a modifier indicating the start of an episode (SOE modifier) for the PC once the treatment planning service is furnished. We would develop a new HCPCS code (and modifiers, as appropriate) for the PC of each of the included cancer types under the Model. The two payments for the PC of the episode would cover all RT services provided by the physician during the episode. Payment for the PC would be made through the PFS and would only be paid to physicians (as identified by their respective TINs).

Under our proposed billing policy, a Professional participant or Dual participant that furnishes the PC of the episode must bill one of the new RO Model-specific HCPCS codes and SOE modifier. This would indicate within the claims systems that an episode has started. Upon submission of a claim with a RO Model-specific HCPCS codes and SOE modifier, we would pay the first half of the payment for the PC of the episode to the Professional participant or Dual participant. A Professional participant or Dual participant must bill the same RO Model-specific HCPCS code that initiated the episode with a modifier indicating the end of an episode (EOE) after the end of the 90-day episode. This would indicate that the episode has ended. Upon submission of a claim with a RO Model-specific HCPCS codes and EOE modifier we would pay the second half of the payment for the PC of the episode to the Professional participant or Dual participant.

Under our proposed billing policy, a Technical participant or a Dual participant that furnishes the TC of an episode must bill a new model-specific HCPCS code with a SOE modifier. We would pay the first half of the payment for the TC of the episode when a Technical participant or Dual participant furnishes the TC of the episode and bills for it using model-specific HCPCS code with a SOE modifier. We would pay the second half of the payment for the TC of the episode after the end of the episode. The Technical participant or Dual participant must bill the same RO Model-specific HCPCS code with an EOE modifier that initiated the episode. This would indicate that the episode has ended.

Similar to the way PCs are billed, we would develop a new HCPCS codes (and any modifiers) for the TC of each of the included cancer types. Payment for the TC would be made through either the OPPS or PFS to the Technical participant or Dual participant that furnished TC of the episode. The two payments for the TC of the episode would cover the provision of equipment, supplies, personnel, and costs related to the radiation treatment during the episode.

The TC of the episode would begin on or after the date that the PC of the episode is initiated and would last until the PC of the episode concludes. Accordingly, the portion of the episode during which the TC is furnished may be up to 90 days long, but could be shorter due to the time between when the treatment planning service is furnished to the RO beneficiary and when RT treatment begins. This is because the treatment planning service and the actual RT treatment do not always occur on the same day.

RO participants would be required to submit encounter data (no-pay) claims that include all RT services identified on the RO Model Bundled HCPCS list (Table 2) as services are furnished and would otherwise be billed under the Medicare FFS systems. We will monitor trends in utilization of RT services during the Model. These claims will not be paid because the bundled payments cover RT services provided during the episode. The encounter data would be used for evaluation and model monitoring, specifically trending utilization of RT services, and other CMS research.

If a RO participant provides clinically appropriate RT services during the 28 days after an episode ends, then the RO participant must bill Medicare FFS for those RT services. A new episode may not be initiated during the 28 days after an episode ends. As we explain in section III.C.5.b.(3). of this proposed rule, we refer to this 28 day period as the ''clean period.''

In the event that a RO beneficiary changes RT provider or RT supplier after the SOE claim has been paid, CMS would subtract the first episode payment paid to the RO participant from the FFS payments owed to the RO participant for services furnished to the beneficiary before the transition occurred and listed on the no-pay claims. This would occur during the annual reconciliation process described in section III.C.11. of this proposed rule. The subsequent provider or supplier (whether or not they are a RO participant) would bill FFS for furnished RT services.

Similarly, in the event that a beneficiary dies, enters hospice, or chooses to defer treatment after the PC has been initiated and the SOE claim paid but before the TC of the episode has been initiated (also referred to as an incomplete episode), during the annual reconciliation process CMS would subtract the first episode payment paid to the Professional participant or Dual participant from the FFS payments owed to that RO participant for services furnished to the beneficiary and listed on the no-pay claims before the transition occurred.

In the event that traditional Medicare stops being the primary payer after the SOE claims for the PC and TC were paid, any submitted EOE claims would be returned and the RO participant(s) would only receive the first episode payment, regardless of whether treatment was completed. If a beneficiary dies or enters hospice after both PC and TC of the episode have been initiated, the RO participant(s) may bill EOE claims and be paid the second half of the episode payment amounts regardless of whether treatment was completed. This is because death and hospice are included in the case mix adjuster.

There may be instances where new providers and suppliers begin furnishing RT services in a CBSA selected to participate in the RO Model. These new providers and suppliers would be RO participants and would have to be identified as such in the claims systems. When a claim is submitted with a RO Model-specific HCPCS code for a site of service that is located within one of the randomly selected CBSAs as identified by the service location's ZIP Code, but the CCN or TIN is not yet identified as a RO participant in the claims systems, the claim would be paid using the rate assigned to that RO Model-specific HCPCS code without the adjustments. Once we are aware of these new providers and suppliers, they will be identified in the claims system and will be paid using Model-specific HCPCS code with or without the adjustments, depending on whether the TIN or CCN new to the Model is a result of a merger, acquisition, or other new clinical or business relationship and there is sufficient data to calculate those adjustments as described in the pricing methodology section III.C.6. of this proposed rule.

Lists of RO Model-specific HCPCS codes would be made available on the RO Model website prior to the model performance period. In addition, we expect to provide RO participants with additional instructions for billing the RO Model-specific HCPCS codes through the Medicare Learning Network (MLN Matters) publications, model-

specific webinars, and the RO Model website.

8. Quality

The quality measures we propose in this proposed rule, along with the proposed clinical data elements in section III.C.8.e, would be scored according to the methodology proposed in section III.C.8.f to calculate the Aggregate Quality Score (AQS). The AQS would be applied to the quality withhold described in section III.C.6.g.(2). of this proposed rule to calculate the quality reconciliation payment amount due to a Professional participant or Dual participant as specified in section III.C.11. of this proposed rule. Results from selected patient experience measures based on the CAHPS® Cancer Care Survey would be incorporated into the AQS for Professional participants and Dual participants starting in PY3. For Technical participants, results from these patient experience measures would be incorporated into the AQS starting in PY3 and applied to the patient experience withhold described in section III.C.6.g.(3). of this proposed rule.

a. Proposed Measure Selection

We propose to adopt the following set of quality measures for the RO Model in order to assess the quality of care provided during episodes. We would begin requiring annual quality measure data submission by Professional participants and Dual participants in March of 2021 for episodes starting and ending inPY1, Quality measures will continue requiring annual data submissions thereafter through the remainder of the model performance period as described in section III.C.8.c. of this proposed rule These quality measures would be used to determine a RO participant's AQS, proposed in section III.C.8.f. of this proposed rule, and subsequent quality reconciliation amount, described in section III.C.11. of this proposed rule. Based on the considerations set forth in this rule, we propose the following measures for the RO Model beginning in PY1 and continuing thereafter:

- Oncology: Medical and Radiation—Plan of Care for Pain—*NQF*[41] *#0383; CMS Quality ID #144*
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan—*NQF #0418; CMS Quality ID #134*
- Advance Care Plan—*NQF #0326; CMS Quality ID #047*
- Treatment Summary Communication—Radiation Oncology

We are proposing to adopt these quality measures for the RO Model for two reasons. First, the Model is designed to preserve or enhance quality of care, and quality measures would allow us to quantify the impact of the Model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems. Second, as discussed in section III.C.9 of this proposed rule, we intend for the RO Model to qualify as an Advanced APM, and also meet the criteria to be a MIPS APM. As stated previously, we believe the proposed quality measures would satisfy the quality measure-related requirements for both an Advanced APM and a MIPS APM. We believe that the following proposed measures meet the requirements of 42 CFR 414.1415(b)(2): (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. These measures are already adopted in MIPS, and we believe the other proposed measure is evidence based, reliable, and valid. We note, however, that we have not proposed an outcome measure for the RO Model. Under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment to participants for covered professional services under the terms of the APM must include at least one additional measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Because we have determined there are currently no outcome measures available or applicable for the RO Model, this requirement does not apply to the RO Model. However, if a relevant outcome measure becomes available, we would consider it for inclusion in the RO Model's measure set if deemed appropriate.

We believe our proposed use of quality measures as described in our proposed AQS scoring methodology in section III.C.8.f. of this proposed rule would meet the quality measure and cost/utilization requirement for a MIPS APM under section 42 CFR 414.1370(b)(3).

In selecting the proposed measure set for the RO Model, we sought to prioritize quality measures that have been endorsed by a consensus-based entity or have a strong evidence-based focus and have been tested for reliability and validity. We focused on measures that would provide insight and understanding into the Model's effectiveness and that would facilitate achievement of the Model's care quality goals. We also sought to include quality measures that align with existing quality measures already in use in other CMS quality reporting programs such as MIPS so that Professional participants and Dual participants would be familiar with the measures used in the Model. Lastly, we considered cross-cutting measures that would allow comparisons of quality across episode payment models and other CMS model tests.

While we believe the proposed measure set would provide the Model with sufficient measures for the model performance period to monitor quality improvement in the radiation oncology sector, and to calculate scoring on quality performance, we intend to adjust the measure set in future PYs by adding new measures or removing measures if we determine those adjustments to be appropriate at the time. Prior to adding or removing measures we would use notice and comment rulemaking.

Table 7 includes the four proposed RO Model quality measures and CAHPS® Cancer Care Survey, the level at which measures would be reported, and the measures' status as pay-for-reporting or pay-for-performance, as described in section III.C.8.b. of this proposed rule. The table also includes the RO Model clinical data elements collection, proposed in section III.C.8.e. of this proposed rule.

[41] National Quality Forum.

TABLE 7. RO PARTICIPANT QUALITY MEASURE, CLINICAL DATA, AND PATIENT EXPERIENCE SUBMISSION REQUIREMENTS

RO Participant Data Submission Requirements	Level of Reporting	Pay-for Reporting	Pay-for-Performance
1. Oncology: Medical and Radiation - Plan of Care for Pain- NQF #0383; CMS Quality ID #144	Aggregate	N/A	PYs 1-5
2. Preventive Care and Screening: Screening for Depression and Follow-Up Plan- NQF #0418; CMS Quality ID #134	Aggregate	N/A	PYs 1-5
3. Advance Care Plan- NQF #0326; CMS Quality ID #047	Aggregate	N/A	PYs 1-5
4. Treatment Summary Communication – Radiation Oncology	Aggregate	PYs 1-2	PYs 3-5
5. CAHPS Cancer Care Survey	N/A: Patient-Reported	N/A	PYs 3-5
Clinical Data Elements	Beneficiary-Level	PYs 1-5	N/A

b. Proposed RO Model Measures and CAHPS® Cancer Care Survey for Radiation Therapy

In this section, we describe more fully the proposed quality measures that we propose to use in the RO Model for purposes of designing a model that could qualify as an Advanced APM and a MIPS APM, and for measuring quality of care. We describe each measure and our reasons for its proposed selection in this proposed rule. We also describe the CAHPS® Cancer Care Survey for Radiation Therapy and our proposal to administer the survey as part of the Model.

We selected these proposed quality measures for the RO Model after conducting a comprehensive environmental scan that included stakeholder and clinician input and compiling a measure inventory. Three of the four measures that we are proposing are currently NQF-endorsed [42] process measures approved for MIPS.[43] The three NQF-endorsed measures approved for MIPS (Plan of Care for Pain; Screening for Depression and Follow-Up Plan; and Advance Care Plan) will be applied as pay-for-performance, given that baseline performance data exists.[44] The fourth measure in the RO Model (Treatment Summary Communication) will be applied as pay-for-reporting until such time that a benchmark can be developed, which is expected to be PY3, as discussed in section III.C.8.f.(1). of this proposed rule. All four measures are clinically appropriate for RT. We selected these measures based on clinical appropriateness to cover RT spanning the 90-day episode period. These measures ensure coverage across the full range of cancer types included in the RO Model and provide us the ability to accurately measure changes or improvements related to the Model's aims. In addition, we are also proposing the CAHPS® Cancer Care Survey to collect information that we believe is appropriate and specific to a patient's experience during an RT episode. We believe these measures and the CAHPS® Cancer Care Survey [45] would allow the RO Model to develop an aggregate quality score (AQS) in our pay-for-performance methodology (described in section III.C.8.f.) that incorporates performance measurement with a focus on clinical care and patient experience.

(1) Proposed Oncology: Medical and Radiation—Plan of Care for Pain (NQF #0383; CMS Quality ID #144)

We propose to adopt the Oncology: Medical and Radiation—Plan of Care for Pain measure in the RO Model. The Oncology: Medical and Radiation—Plan of Care for Pain is a process measure that assesses whether a plan of care for pain has been documented for patients with cancer who report having pain. This measure assesses the ''[p]ercentage of patients, regardless of age, with a diagnosis of cancer who are currently receiving chemotherapy or RT that have moderate or severe pain for which there is a documented plan of care to address pain in the first two visits.'' [46] As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50843), pain is the most common symptom in cancer, occurring in approximately one quarter of patients with newly diagnosed malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease.[47] Proper pain

[42] NQF endorsement summaries: *http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx.*

[43] See the CY 2018 QPP final rule (82 FR 53568).

[44] Baseline performance is based on the entirety of data submitted to meet MIPS data reporting requirements for these measures and are not specific to radiation oncology performance.

[45] As discussed in section III.C.8.b(5) and III.C.8.f, the CAHPS® Cancer Care Survey would be administered beginning in April 1, 2020, and we would seek to include measures in the aggregate quality score beginning inPY3.

[46] Oncology: Medical and Radiation—Plan of Care for Pain. American Society of Clinical Oncology. In Review for Maintenance of Endorsement by the National Quality Forum (NQF #0383). Last Updated: June 26, 2018.

[47] Swarm RA, Abernethy AP, Anghelescu DL, et al. Adult Cancer Pain: Clinical Practice Guidelines in Oncology. *Journal of the National*

Continued

management is critical to achieving pain control. This measure aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment.

We believe this measure is appropriate for inclusion in the RO Model because it is specific to a RT episode of care. It considers the quality of care of medical and radiation oncology and is NQF endorsed. The RO Model would adopt the measure according to the most recent version of the specifications, which is under review at NQF in Fall 2019. The current measure version is being used for payment determination within the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (beginning in FY2016 as PCH–15), the Oncology Care Model (OCM) (beginning in 2016 as a component of OCM–4), and the Merit-based Incentive Payment System (MIPS) (beginning in CY2017 as CMS #144). As long as the measure remains reliable and relevant to the RO Model's goals, we would continue to include the measure in the Model regardless of whether or not the measure is used in other CMS programs. If we believed that it was necessary to remove the measure from the RO Model, then we would propose to do so through notice and comment rulemaking.

This measure is currently undergoing triennial review for NQF endorsement, and while we expect changes to the measure specifications, we do not believe these changes would change the fundamental basis of the measure, nor do we believe they would impact the measure's appropriateness for inclusion in the RO Model. NQF endorsement is a factor in our decision to propose the Medical and Radiation—Plan of Care for Pain measure, but it is not the only factor, so if the measure were to lose its NQF endorsement, we may choose to retain it so long as we believe it continues to support CMS and HHS policy goals. Therefore, we propose to adopt the Plan of Care for Pain measure with the associated specifications available beginning in PY1. This measure will be a pay-for-performance measure and scored in accordance with our proposed methodology in section III.C.8.f.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data to the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Plan of Care for Pain measure specification states the data would be reported for the performance year that covers the date of encounter. The measure numerator includes patient visits that included a documented plan of care to address pain. The measure denominator includes all visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain. Any exclusions can be found in the detailed measure specification linked in this section of this proposed rule.

For the RO Model, we propose to use the registry specifications for this measure. Detailed measure specifications may be found at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_144_Registry.pdf.*

(2) Proposed Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134)

We propose to adopt the Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure in the RO Model. The Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure is a process measure that assesses the ''[p]ercentage of patients screened for clinical depression with an age-appropriate, standardized tool and who have had a follow-up care plan documented in the medical record.'' [48] We believe this clinical topic is appropriate for a RT episode of care even though it is not specific to RT. While this measure is drafted for consideration of general mental health, it can also be applied to RT. Because some of the side effects of RT have been identified as having a detrimental effect on a patient's quality of life and could potentially impact the patient beyond physical discomfort or pain, we believe inclusion of this measure is desirable to screen and treat the potential mental health effects of RT. [49] [50] [51] [52] [53] [54] This measure has been used for payment determination within OCM (beginning in 2016 as OCM–5) and MIPS (beginning in CY2018 as CMS #134) and is NQF endorsed. As long as the measure remains reliable and relevant to the RO Model's goals, we would continue to include the measure in the Model, regardless of use in other CMS programs. If we were to remove the measure, we would use notice and comment in rulemaking. This measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our proposed methodology in section III.C.8.f.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data to the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure specification states the data would be reported for the performance year that covers the date of encounter. The measure numerator includes patients screened for depression on the date of the encounter using an age-appropriate standardized tool and, if the screening is positive, a follow-up plan is documented on the date of the positive screen. The measure denominator includes all patients aged 12 years and older before the beginning of the measurement period with at least one eligible encounter during the measurement period. Any exclusions can be found in the detailed measure specification linked in this section in this proposed rule.

For the RO Model, we propose to use the registry specifications for this measure. Detailed measure specifications may be found at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_134_Registry.pdf.*

Comprehensive Cancer Network: JNCCN. 2013;11(8):992–1022. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915297/.*

[48] Preventive Care and Screening: Screening for Depression and Follow-Up Plan. Centers for Medicare & Medicaid Services. Endorsed by the National Quality Forum (NQF #0418). Last Updated: Jun 28, 2017.

[49] Siu AL, and the US Preventive Services Task Force USPSTF. Screening for Depression in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2016;315(4):380–387. doi:10.1001/jama.2015.18392.

[50] Meijer, A., Roseman, M., Milette, K., Coyne, J.C., Stefanek, M.E., Ziegelstein, R.C., . . . Thombs, B.D. (2011). Depression screening and patient outcomes in cancer: a systematic review. PloS one, 6(11), e27181. doi:10.1371/journal.pone.0027181.

[51] Li, M., Kennedy, E.B., Byrne, N., Gérin-Lajoie, C., Katz, M.R., Keshavarz, H., . . . Green, E. (2016). Management of Depression in Patients With Cancer: A Clinical Practice Guideline. Journal of Oncology Practice, 12(8), 747–756. doi:10.1200/jop.2016.011072.

[52] Pinquart, M., & Duberstein, P.R. (2010). Depression and cancer mortality: A meta-analysis. Psychological Medicine, 40(11), 1797–1810. doi:10.1017/s0033291709992285.

[53] Massie, M.J. (2004). Prevalence of Depression in Patients With Cancer. Journal of the National Cancer Institute Monographs, 2004(32), 57–71. doi:10.1093/jncimonographs/lgh014.

[54] Linden, W., Vodermaier, A., Mackenzie, R., & Greig, D. (2012). Anxiety and depression after cancer diagnosis: Prevalence rates by cancer type, gender, and age. Journal of Affective Disorders, 141(2–3), 343–351. doi:10.1016/j.jad.2012.03.025.

(3) Proposed Advance Care Plan (NQF #0326; CMS Quality ID #047)

We propose to adopt the Advance Care Plan measure in the RO Model. The Advance Care Plan measure is a process measure that describes percentage of patients aged 65 years and older that have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance 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. This is a cross-cutting measure across all specialties and a variety of settings, but we believe that it appropriate for the RO Model because we believe that it is essential that a patient's wishes regarding medical treatment are established as much as possible prior to incapacity.

This measure is NQF endorsed and has been collected for OCM (beginning in 2018 as OCM–24) and MIPS (beginning in CY2018 as CMS #047), making its data collection processes reasonably well established. As long as the measure remains reliable and relevant to the RO Model's goals, we would continue to include the measure in the Model, regardless of use in other CMS programs and initiatives. If we believed it was necessary to remove the measure from the Model, we would propose to do so through notice and comment rulemaking. This measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our proposed methodology in section III.C.8.f.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Advance Care Plan measure specification states the data would be reported for the performance year that covers the date of documentation in the medical record. The measure numerator includes patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. The measure denominator includes all patients aged 65 years and older. Any exclusions can be found in the detailed measure specification linked in this section of this proposed rule.

For the RO Model, we propose to use the registry specifications for this measure. Detailed measure specifications may be found at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_047_Registry.pdf.*

(4) Proposed Treatment Summary Communication—Radiation Oncology

We propose to adopt the Treatment Summary Communication—Radiation Oncology measure in the RO Model. The Treatment Summary Communication measure is a process measure that assesses the ''[p]ercentage of patients, regardless of age, with a diagnosis of cancer that have undergone brachytherapy or external beam RT who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment.'' [55] We believe this measure is appropriate for inclusion in the RO Model because it is specific to a RT episode of care. This measure assesses care coordination and communication between providers during transitions of cancer care treatment and recovery. While this measure is not NQF endorsed, and has not been used in previous or current CMS quality reporting, it has been used in the oncology field for quality improvement efforts, making considerations regarding data collection reasonably well established. We propose to include the measure as we believe it to be valid and relevant to the RO Model's goals. This measure will be the one pay-for reporting measure included in the calculation of the AQS until a benchmark is established that would enable it to be pay-for-performance, which is expected to be beginning in PY3.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data to the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Treatment Summary Communication measure specification states the data would be reported for the performance year that covers the date of the treatment summary report in the chart. The measure numerator includes patients who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment. The measure denominator includes all patients, regardless of age, with a diagnosis of cancer who have undergone brachytherapy or external beam radiation therapy. Any exclusions can be found in the detailed measure specification linked in this section of this proposed rule.

For the RO Model, we propose to use the registry specifications for this measure. Detailed measure specifications may be found at: *http://www.qualityforum.org/QPS/0381.*

(5) Proposed CAHPS® Cancer Care Survey for Radiation Therapy

We propose to have a CMS-approved contractor administer the CAHPS® Cancer Care Survey for Radiation Therapy (''CAHPS® Cancer Care survey'') beginning April 1, 2020 and ending in 2025 to account for episodes that were completed in the last quarter of 2024. We are proposing the CAHPS® cancer care survey for inclusion in the Model as it is appropriate and specific to patient experience of care within a RT episode. Variations of the CAHPS® survey are widely used measures of patient satisfaction and experience of care and are responsive to the increasing shift toward incorporation of patient experience into quality measurement and pay-for-performance programs. Variations of the CAHPS® survey have been used within the PCHQR Program, Hospital OQR Program, MIPS, OCM, and others, making considerations regarding data collection reasonably well established.

In future rulemaking, we plan to propose a set of patient experience measures based on the CAHPS® Cancer Care survey, which would be included in the AQS as pay-for-performance measures beginning in PY 3.

The CAHPS® Cancer Care survey proposed for inclusion in the RO Model may be found at *https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html.*

We invite public comment on our proposal to administer the CAHPS® Cancer Care Survey for Radiation Therapy for purposes of testing the RO Model.

c. Proposed Form, Manner, and Timing for Quality Measure Data Reporting

We propose the following data collection processes for the four proposed quality measures described in section III.C.8.b.(1) through (4). of this proposed rule beginning in PY1.

First, we propose to require Professional participants and Dual

[55] Oncology: Treatment Summary Communication—Radiation Oncology. American Society for Radiation Oncology. Endorsement removed by the National Quality Forum (NQF #0381). Last Updated: Mar 22, 2018.

participants to report aggregated quality measure data, instead of beneficiary-level quality measure data. These data will be used to calculate the participants' quality performance as discussed in section III.C.8.f.(1). of this proposed rule and subsequent quality reconciliation payments on an annual basis.

Second, we propose to require that data be reported for all applicable patients (for example, not just Medicare beneficiaries or beneficiaries with radiation episodes under the Model) based on the numerator and denominator specifications for each measure. We believe collecting data for all patients who meet the denominator specifications for each measure from a Professional participant or Dual participant, and not just Medicare beneficiaries, is appropriate because it is consistent with the applicable measure specifications, and any segmentation to solely the Medicare populations would be inconsistent with the measure and add substantial reporting burden to RO participants. If a measure is already reported in another program, then the measure data would be submitted to that program's reporting mechanism in a form, manner, and at a time consistent with the other program's requirements, and separately submitted to the RO Model reporting portal in the form, manner and at the time consistent with the RO Model requirements.

Similar to the approach taken for the Quality Payment Program,[56] the RO Model would not score measures for a given Professional participant or Dual participant that does not have at least 20 applicable cases according to each measure's specifications. However, unlike the Quality Payment Program, if measures do not have at least 20 applicable cases for the participant, we would not require the measures to be reported. In this situation, an RO participant would enter ''N/A-insufficient cases'' to note that an insufficient number of cases exists for a given measure.

We would provide Professional participants and Dual participants with a mechanism to input quality measure data. We would create a template for Professional participants and Dual participants to complete with the specified numerator and denominator for each quality measure (and the number of cases excluded and exempt from the denominator, as per measure specifications exclusions and exemptions allowances), provide a secure portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the data prior to the first data submission period.

We propose that Professional participants and Dual participants would be required to submit quality measure data annually by March 31 following the end of the previous PY to the RO Model measure submission portal. In developing the March 31 deadline, we considered the quality measure reporting deadlines of other CMS programs in conjunction with the needs of the Model. For PY1, participants would submit quality measure data for the time period noted in the measure specification. Thus, if a measure is calculated on an annual CY basis, participants would not adjust the reporting period to reflect the model time period. We anticipate this adherence to the measure specifications used in MIPS would reduce measure reporting burden for RO participants. In the event that the model implementation begins on April 1, 2020, the calendar year submission would remain; this would allow RO participants to use their MIPS data submission to meet the RO Model requirements. We believe that any segmentation to reflect only the RO Model time period in PY1 would be inconsistent with the measure, and add substantial reporting burden to RO participants. RO participants would submit data based on the individual measure specifications as previously discussed, unless otherwise announced by CMS. RO Model measure submissions would only satisfy the RO Model requirements. Measures submitted to any other CMS program would need to continue to be made in accordance with that program's requirements unless specifically noted. A schedule for data submission would be posted on the RO Model website: *https://innovation.cms.gov/initiatives/radiation-oncology-model/*.

We would determine that Professional participants and Dual participants successfully collected and submitted quality measure data if the data are accepted in the RO Model portal by the reporting deadline of March 31 after the PY. Failure to submit quality measure data within the previously discussed requirements would impact the RO participant's AQS, as discussed in section III.C.8.f.

As discussed in section III.C.8.f, the CAHPS® Cancer Care Survey for Radiation Therapy would be administered by a CMS contractor according to the guidelines set forth in the survey administration guide, or otherwise specified by CMS. Prior to the first administration of the survey, we would perform education and outreach so that RO participants would have the opportunity to become more familiar with the CAHPS® Cancer Care survey process and ask any questions.

d. Proposed Maintenance of Technical Specifications for Quality Measures

As part of its regular maintenance process for NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and would confirm existing or minor specification changes with NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific three-year cycle. We note that NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures. Additionally, the Model includes measures that are not NQF-endorsed, but we anticipate that they will similarly require non-substantive technical updates to remain current.

e. Proposed Clinical Data Collection

In addition to collecting quality measure data, we also propose under § 512.275(c) to collect clinical information on certain RO beneficiaries included in the Model from Professional participants and Dual participants that furnish the PC of an episode for use in the RO Model's pay-for-reporting approach and for monitoring and compliance, which we discuss more fully in sections III.C.8.f(1) and section III.C.14, respectively.

On a pay-for-reporting basis, we would require Professional participants and Dual participants to report basic clinical information not available in claims or captured in the proposed quality measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) Prostate, (2) breast, (3) lung, (4) bone metastases, and (5) brain metastases. We would determine the specific data elements and reporting standards prior to the start of the Model and would communicate them on the Model website.

In addition, we would provide education, outreach, and technical assistance. We believe this information

[56] 42 CFR 414.1380(b)(1)(iii).

is necessary to achieve the Model's goals of eliminating unnecessary or low-value care. We have also heard from many stakeholders that they believe incorporating clinical data is important for developing accurate episode prices and understanding the details of care furnished during the episode that are not available in administrative data sources. We would use these data to support clinical monitoring and evaluation of the RO Model. These data may also be used to inform future refinements to the Model. We may also use it to begin developing and testing new radiation oncology-specific quality measures during the Model.

To facilitate data collection, we plan to share the proposed clinical data elements and reporting standards with EHR vendors and the radiation oncology specialty societies prior to the start of the Model. Our goal would be to structure data reporting standards so that existing EHRs could be adjusted in anticipation of this Model. Such changes could allow for seamless data extraction and reduce the additional reporting burden on providers and may increase the quality of reporting. Providers may also opt to extract the necessary data elements manually. All Professional participants and Dual participants with RO beneficiaries treated for the five cancer types as previously listed would be required to report clinical data through a model-specific data collection system. We would create a template for RO participants to complete with the specified clinical data elements, provide a secure portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the data prior to the first data submission period.

We are also proposing to establish reporting standards. We propose that all Professional participants and Dual participants must submit clinical data information biannually, in July and January, each PY for RO beneficiaries with the applicable cancer types that completed their 90-day episode within the previous six months. This would be in addition to the quality measure data as described in section III.C.8.c.

We are specifically interested in feedback on the five cancer types where we propose to collect clinical data, which data elements should be captured for the five cancer types, and potential barriers to collecting data of this type.

We invite comments on our proposal to collect clinical data.

f. Proposal To Connect Performance on Quality Measures to Payment

(1) Proposed Calculation for the Aggregate Quality Score

The AQS would be based on each Professional participant's and Dual participant's: (1) Performance on the set of proposed evidenced-based quality measures in sections III.C.8.b(1), (2), and (3) of this proposed rule compared to those measures' quality performance benchmarks; (2) reporting of data for the proposed pay-for-reporting measures (those without established performance benchmarks) in section III.C.8.b.(4) of this proposed rule; and (3) reporting of clinical data elements on applicable RO beneficiaries proposed in section III.C.8.e. of this proposed rule.

A measure's quality performance benchmark is the performance rate a Professional participant or Dual participant must achieve to earn quality points for each measure proposed in section III.C.8.b.[57] We believe a Professional participant's or Dual participant's performance on these quality measures, as well as successful reporting of pay-for-reporting measures and clinical data elements, would appropriately assess the quality of care provided by the Professional participant or Dual participant.

Given the importance of clinical data for monitoring and evaluation of the RO Model, and the potential to use the data for model refinements or quality measure development, we propose to weight 50 percent of the AQS on the successful reporting of required clinical data and the other 50 percent of the AQS on quality measure reporting and, where applicable, performance on those measures. Mathematically, this weighting would be expressed as follows:

Aggregate Quality Score = Quality measures (0 to 50 points based on weighted measure scores and reporting) + Clinical data (50 points when data is submitted for ≥95% of applicable RO beneficiaries)

Quality measures would be scored as pay-for-performance or pay-for-reporting, depending on whether established benchmarks exists, as proposed in section III.C.8. To score measures as pay-for-performance, each Professional participant's and Dual participant's performance rates on each measure would be compared against applicable MIPS program benchmarks, where such benchmarks are available for the measures. The measures proposed as pay-for-performance for PY1 are selected from the list of MIPS quality measures: (1) Advance Care Plan; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; (3) Oncology: Medical and Radiation—Plan of Care for Pain. The MIPS program awards up to ten points (including partial points) to participants for their performance rates on each measure, and we would score RO participants' quality measure performance similarly using MIPS benchmarks.[58] For example, when a Professional participant's or Dual participant's measured performance reaches the performance level specified for three points, we will award the participant three points. If applicable MIPS benchmarks are not available, we would use other appropriate national benchmarks for the measure where appropriate. If a national benchmark is not available, we would calculate Model-specific benchmarks from the previous year's historical performance data. If historical performance data are not available, then we would score the measure as pay-for-reporting and would provide credit to the Professional participant or Dual participant for reporting the required data for the measure. We intend to specify quality measure data reporting requirements on the RO Model website. Once benchmarks are established for the pay-for-reporting measures, we would seek to use the benchmarks to score the measures as pay-for-performance in subsequent years.

As stated earlier in this rule, measures may be scored as pay-for-reporting (instead of pay-for-performance). Professional participants and Dual participants that report the measure in the form, time, and manner specified in the measure specification would receive ten points for the measure. Professional participants and Dual participants that do not submit the measure in the form, time, and manner specified would receive zero points. As proposed in section III.C.8.b(4), the Treatment Summary Communication measure would be the only pay-for-reporting measure in PY1.

The total points awarded for each measure included in the AQS would also depend on the measure's weight. We propose to weight all four of our proposed quality measures (those deemed pay-for-performance as well as pay-for-reporting) equally and aggregate

[57] Benchmarks will be based on existing MIPS benchmarks, or other national benchmark where available. For measures without existing benchmarks, we plan to develop our own benchmarks.

[58] The benchmarks are published annually at this CMS site: *https://qpp.cms.gov/about/resource-library.*

them as half of the AQS. To accomplish that aggregation as half of the AQS, we would award up to 10 points for each measure, then recalibrate Professional participants' or Dual participants' measure scores to a denominator of 50 points. CAHPS® Cancer Care Survey for Radiation Therapy results discussed in section III.C.8.b(5) would be added into the AQS beginning in PY3 and we would propose the specific weights of the selected measures from the CAHPS® survey in future rulemaking. We would also propose specific weights for additional measures if and when the Model adopts additional measures in the future.

In cases where Professional participants and Dual participants do not have sufficient cases for a given measure—for example, if a measure requires 20 cases during the applicable period for its calculation to be sufficiently reliable for performance scoring purposes—that measure would be excluded from the AQS denominator calculation and the denominator would be recalibrated accordingly to reach a denominator of 50 points. This recalibration is intended to ensure that Professional participants and Dual participants do not receive any benefit or penalty for having insufficient cases on a given measure.

For example, a Professional participant or Dual participant might have sufficient cases to report numerical data on three measures, meaning that it has a total of 30 possible points for the quality measures component of its AQS. If the Professional participant or Dual participant received scores on those measures of nine points, four points, and seven points, it would have scored 20 out of 30 possible points on the quality measures component. That score is equivalent to 33.33 points after recalibrating the denominator to 50 points ((20/30) * 50 = 33.33). In instances where a Professional participant or Dual participant fails to report quality reporting data for a measure, it would receive 0 out of 10 for that measure in the quality portion of the AQS, and the denominator would remain at 40 points, which would then be recalibrated to 50 points. For example, if the same Professional participant or Dual participant scored 20 points out of 40 possible points, it would be equivalent to 25 points after recalibrating the denominator to 50 points ((20/40) * 50 = 25).

Our assessment of whether the Professional participant or Dual participant has successfully reported clinical data would be based on whether the participant has submitted the data in the time period identified and has furnished the data elements to us as requested, which we discuss in section III.C.8.c. Professional participants and Dual participants would either be considered ''successful'' reporters and receive full credit for meeting our requirements, or ''not successful'' reporters and not receive credit. We propose to define successful reporting as the submission of clinical data for 95 percent of RO beneficiaries with any of the five diagnoses listed in section III.C.8.e. If the Professional participant or Dual participant does not successfully report sufficient clinical data to meet the 95 percent threshold, it would receive 0 out of 50 points for the clinical data elements component of the AQS.

To calculate the AQS, we propose to sum each Professional participant's or Dual participant's points awarded for clinical data reporting with its aggregated points awarded for quality measures to reach a value that would range between 0 and 100 points. As discussed earlier in this rule, we would recalibrate the points we award for measures to a denominator of 50 points. We would then divide the AQS by 100 points to express it as a percentage.

To illustrate the calculation of the AQS score two examples are included in this rule. Table 8 details the AQS calculation for a Professional participant or Dual participant that did not meet the minimum case requirements for one of the pay-for-performance measures.

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TABLE 8 EXAMPLE: AQS CALCULATION DETAILS

ALL NUMBERS ARE ILLUSTRATIVE ONLY

	Notes	Participant Score	Maximum Points	Formula
Quality Measures				
Measure 1 (a)	Pay-for-performance	10	10	
Measure 2 (b)	Pay-for-performance	3	10	
Measure 3 (c)	Pay-for-performance *Did not meet minimum case requirements*	0	0	
Measure 4 (d)	Pay-for-reporting	10	10	
Subtotal (e)		23	30	e = a+b+c+d
Weighted to 50% (f)		38.3	50	f = (participant score of e* 50) / maximum points of e
Clinical Data Elements (g)	≥95% of applicable RO beneficiaries	50	50	
Total (h)		88.3	100	h = f+g
AQS (i)		88.3%		i = participant score of h/maximum points of h

Table 9 details the AQS calculation for a Professional participant or Dual participant that did not meet the reporting requirements for the clinical data elements and the pay-for-reporting measure.

TABLE 9 EXAMPLE: AQS CALCULATION DETAILS

ALL NUMBERS ARE ILLUSTRATIVE ONLY

	Notes	Participant Score	Maximum Points	Formula
Quality Measures				
Measure 1 (a)	Pay-for-performance	4.5	10	
Measure 2 (b)	Pay-for-performance	5	10	
Measure 3 (c)	Pay-for-performance	1	10	
Measure 4(d)	Pay-for-reporting *Did not report data as required*	0	10	
Subtotal (e)		10.5	40	e = a+b+c+d
Weighted to 50% (f)		13.1	50	f = (participant score of e* 50) / maximum points of e
Clinical Data Elements (g)	<95% of applicable RO beneficiaries	0	50	
Total (h)		13.1	100	h = f+g
AQS (i)		13.1%		i = participant score of h/maximum points of h

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We believe that this method has the benefits of simplicity, normalization of differences in reported measures between RO participants, and appropriate incorporation of clinical data reporting.

We invite public comment on the proposed calculation for the AQS methodology.

(2) Proposal To Apply the AQS to the Quality Withhold

We propose the following method to apply the AQS to the amount of the quality withhold that could be earned back by a RO participant. We would multiply the Professional participant's or Dual participant's AQS (as a percentage) against the 2 percent quality withhold amount. For example, if a Professional participant or Dual participant received an AQS of 88.3 out of a possible 100, then the Professional participant or Dual participant would receive a 1.77 percent quality reconciliation payment amount (0.883 * 2.0 = 1.77%). If the total episode payment amount for this RO participant after applying the trend factor, adjustments, and discount factor was $2,465.68,[59] the example AQS of 88.3 would result in a quality reconciliation payment amount of $43.64 ($2,465.68 * 1.77% = $43.64).[60]

We would continue to weight measures equally in PY1 through PY5 unless we determine that the Model needs to emphasize specific clinical transformation priorities or add new measures. Any updates to the scoring methodology in future PYs would be proposed and finalized through notice-and-comment rulemaking. There may be some variation in the measures that we score to calculate the AQS for Professional participants and Dual participants should they be unable to report numerical data for certain measures due to sample size constraints or other reasons. However, we do not anticipate that variation will create any methodological problems for the Model's scoring purposes.

The AQS would be calculated approximately eight months after the end of each PY and applied to calculate the quality withhold payment amount for the relevant PY. Any portion of the quality withhold that is earned back would be distributed in an annual lump sum during the reconciliation process as described in section III.C.11.

We invite public comments on our proposal to apply the AQS to the amount of the quality withhold proposed in section III.C.6.g(2).

9. The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-Based Incentive Payment System APM (MIPS APM)

We anticipate that the RO Model would be both an Advanced APM and a MIPS APM. For purposes of the Quality Payment Program, we propose that the RO participant, specifically either a Dual participant or a Professional participant, would be the APM Entity.

We propose to establish an ''individual practitioner list'' under the RO Model, created by CMS and sent to Dual participants and Professional participants to review, revise, certify, and return to CMS so that CMS may make QP determinations for the APM incentive payment amount and to identify any MIPS eligible clinicians who would be scored for MIPS based on their participation in this MIPS APM. If finalized as proposed, the individual practitioner list would serve as the Participation List as defined in the regulation at section 414.1305 for the Model. We propose to codify the term ''individual practitioner list'' for purposes of the RO Model in § 512.205 of our regulations.

The individuals included on the individual practitioner list would include physician radiation oncologists that are eligible clinicians participating in the RO Model with either a Dual participant or a Professional participant as described in section III.C.5.a of this proposed rule. Eligible clinicians who are identified on the participation list for an Advanced APM during a QP Performance Period may be determined to be Qualifying APM Participants (QPs) as specified in our regulations at 42 CFR 414.1425, 414.1435, and 414.1440. Similarly, MIPS eligible clinicians who are identified on the participation list for the performance period of an APM Entity participating in a MIPS APM are scored for MIPS using the APM scoring standard as provided in our regulation at 42 CFR 414.1370. Only Professional participant physicians and Dual participant physicians included on the individual practitioner list would be considered eligible clinicians.

We propose that prior to the start of each PY, we would create and provide each Dual participant and Professional participant with an individual practitioner list. The Dual participants and Professional participants must review and certify the individual participant list within 30 days of receipt of such list in a form and manner specified by CMS. In the case of a Dual participant or Professional participant that begins the RO Model after the start of PY, but at least 30 days prior to the final QP snapshot date of that PY, CMS would create and provide the new Dual participant or Professional participant with an individual practitioner list.

In order to certify the list, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the list. The certified individual practitioner list would include all individual practitioners who have reassigned their rights to receive Medicare payment for the provision of RT services to the TIN of the RO participant. The individual with the authority to bind the RO participant must agree to comply with the requirements of the RO Model before the RO participant certifies the list. We note that we are not proposing that HOPDs that are Technical participants be a part of this list process because as HOPDs they are paid by OPPS, which is not subject to the Quality Payment Program. We propose that RO participants may make changes to the individual practitioner list that has been certified at the beginning of the performance year. In order to make additions to the list, the RO participant must notify CMS within 15 days of an individual practitioner becoming a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely addition will be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the addition, the addition is effective on the date of the notice. The notice must be submitted in a form and manner specified by CMS.

In order to remove an individual practitioner from the list, the RO participant must notify CMS within 15 days if an individual practitioner ceases to be a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely removal will be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the removal, the removal is effective on the date of the notice. The notice must be submitted in a form and manner specified by CMS. Further, we propose that the RO participant must ensure that the individuals included on the individual practitioner list maintain compliance with the regulation at § 424.516, including notifying CMS of any

[59] This number refers to the result in line (j) in Table 5.

[60] This number is prior to the geographic adjustment and sequestration being applied.

reportable changes in status or information. The certified individual practitioner list would be used for purposes related to QP determinations as specified in 42 CFR part 414 subpart O. We further propose that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, the unverified list would be used for scoring under MIPS using the APM scoring standard. We propose to codify these provisions relating to the individual practitioner list at § 512.217.

In order to be an Advanced APM, the RO Model must meet the criteria specified in our regulation at 42 CFR 414.1415. First, in order to be an Advanced APM, an APM must require participants to use certified EHR technology (CEHRT). For QP Performance Periods beginning in 2019, to meet this requirement, an Advanced APM must require at least 75 percent of eligible clinicians in the APM Entity or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers pursuant to 42 CFR 414.1415(a)(1)(i). We propose that during the model performance period, the RO participant would be required to annually certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Further, we propose that within 30 days of the start of PY1, the RO participant would be required to certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Annual certification would be required prior to the start of each subsequent PY.

We solicit public comments on this proposal.

Second, to be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM as specified at 42 CFR 414.145(b)(1). Effective January 1, 2020, at least one of the quality measures upon which the APM bases payment must meet at least one of the following criteria: (a) Finalized on the MIPS final list of measures, as described in 42 CFR 414.1330; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidenced-based, reliable, and valid.

We discuss the RO Model's proposed quality measure set in section III.C.8.b. We intend to use the results of the following proposed quality measures when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f.: (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan; and (4) Treatment Summary Communication—Radiation Oncology. Further, the quality measures we propose to use for the RO Model are measures that are either finalized on the MIPS final list of measures, or determined by CMS to be evidence based, reliable, and valid. Specifically, we believe that these measures would meet the criteria under 42 CFR 414.1415(b).

In addition to the quality measure requirements listed earlier, under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment must include at least one outcome measure. This requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the APM's first QP Performance Period. There currently are no such outcome measures available or applicable for the RO Model's first QP Performance Period. If a relevant outcome measure becomes available, we would consider it for inclusion in the RO Model's measure set if deemed appropriate.

Third, the APM must require participating APM Entities to bear financial risk for monetary losses of more than a nominal amount or, be a Medical Home Model expanded under the Innovation Center's authority, in accordance with section 1115A(c) of the Act. We expect that the RO Model would meet the generally applicable financial risk standard in accordance with 42 CFR 414.1415 because there is no minimum (or maximum) financial stop loss for RO participants, meaning RO participants would be at risk for all of the RT services beyond the episode payment amount.

The regulation at 42 CFR 414.1415(c)(1) requires that ''to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following: (i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians; (ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or (iii) Require the APM Entity to owe payment(s) to CMS.'' The RO Model would meet this standard because CMS would not pay the RO participant more for RT services than the episode payment amount.

The regulation at 42 CFR 414.1415(c)(3) sets the standard for a nominal amount of risk for Advanced APMs other than Medical Home Models at either ''eight percent of the average estimated total Medicare Parts A and B revenues of participating APM Entities'' for QP Performance Periods in 2017 through 2024 or ''three percent of the expected expenditures for which the APM Entity is responsible for under the APM'' for all QP Performance Periods.

For the RO Model, we propose that the APM Entities would be at risk for all costs associated with RT services as defined in section III.C.5.c beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, would be at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the aforementioned episode payments. RO participants would not receive any additional payment or reconciliation from CMS (beyond the participant-specific professional episode payment or participant-specific technical episode payment) to account for any additional medically necessary RT services furnished during the 90-day episode. Effectively, this means that when actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures, the RO participant is responsible for 100 percent of those costs without any stop-loss or cap on potential losses. This would satisfy the requirement under 42 CFR 414.1415(c)(3)(i)(B) because, for example, if actual expenditures are 3 percent more, or 5 percent more, or 7 percent more than the expected expenditures for which a RO participant is responsible under the model, the RO participant is 100 percent liable for those additional 3 percent, 5 percent, or 7 percent of costs without any limit to the total amount of losses they may incur.

Additionally, we anticipate that the proposed RO Model would meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1 if the implementation date is finalized as January 1, 2020 or PY2 if finalized as April 1, 2020. MIPS APMs, as defined in 42 CFR 414.1305, are APMs that meet the criteria specified under 42 CFR 414.1370(b). Pursuant to § 414.1370(a), MIPS eligible clinicians who are identified on a participation list for the performance period of an APM

Entity participating in a MIPS APM are scored under MIPS using the APM scoring standard. We propose to use the same individual practitioner list developed as previously proposed, to identify the relevant eligible clinicians for purposes of making QP determinations and applying the APM scoring standard under the Quality Payment Program.

We note that the following proposals would apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

- Our proposals regarding monitoring, audits and record retention, and remedial action, as described in section II.F and III.C.14. Under our proposed monitoring policy, RO participants would be monitored for compliance with the RO Model requirements. CMS may, based on the results of such monitoring, deny an eligible clinician who is participating in the RO Model QP status if the eligible clinician or the eligible clinician's APM entity (that is, the respective RO participant) is non-compliant with RO Model requirements.
- Our proposal in section III.C.10.c, which explains that technical component payments under the RO Model would not be included in the aggregate payment amount for covered professional services that is used to calculate the amount of the APM Incentive Payment.

We invite public comment on these proposals.

10. Proposed Medicare Program Waivers

We believe it would be necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the RO Model under section 1115A(b) of the Act. Each of the waivers, which we discuss in detail, would be necessary to ensure that the Model test's design provides additional flexibilities to RO participants, including flexibilities around certain Medicare program requirements.

a. Proposed Waiver of Hospital Outpatient Quality Reporting (OQR) Program Payment Adjustment

We believe that it is necessary for purposes of testing the RO Model to waive the Hospital OQR Program payment reduction authorized under section 1833(t)(17)(A) of the Act. Under the Hospital OQR Program, subsection (d) hospitals are required to submit data on measures on the quality of care furnished by hospitals in outpatient settings. Further, Section 1833(t)(17)(A)(i) of the Act states that subsection (d) hospitals that fail to meet Hospital OQR Program requirements receive a two percentage point reduction to their outpatient department (OPD) fee schedule increase factor. The fee schedule increase factor is applied annually to increase the OPPS conversion factor, which is then multiplied by the relative payment weight for a particular Ambulatory Payment Classification (APC) to determine the payment amount for the APC. Not all OPPS items and services are included in APCs for which the payment is determined using the conversion factor. For this reason, we only apply the 2 percent reduction to APCs—identified by status indicators—for which the payment is calculated by multiplying the relative payment weight by the conversion factor.

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in a form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for many services under the OPPS. To reduce the OPD fee schedule increase factor for hospitals that fail to meet the Hospital OQR Program reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. Thus, our policy is to apply the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for a year (83 FR 59108–59110).

In this proposed rule, we are proposing that, for purposes of APCs that contain RO Model-specific HCPCS codes, we would waive the requirement under section 1833(t)(17)(A)(i) of the Act that the Secretary reduce the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act or a year by 2.0 percentage points for a subsection (d) hospital that does not submit, to the Secretary in accordance with paragraph (17), data required to be submitted on measures selected under paragraph with respect to such a year. RO Model-specific HCPCS codes would be mapped to RO Model-specific APCs for payment purposes under the OPPS. This waiver would apply only to the APCs that include only the new HCPCS codes that are created for the RO Model, rather than all APCs that package radiation HCPCS codes, and would only apply when a hospital does not meet requirements under the Hospital OQR Program and would otherwise be subject to the 2.0 percentage point reduction. Only Technical participants using the RO Model-specific HCPCS codes would be paid under the Model; APCs not included in the Model, and thus not using the RO Model-specific HCPCS codes, will continue to be paid under the OPPS and subject to the 2.0 percentage point reduction under the Hospital OQR Program when applicable. We believe this waiver is necessary in order to equally evaluate participating HOPDs and freestanding radiation oncology centers on both cost and quality.

The RO Model is a test of a site-neutral pricing methodology, where payment rates are calculated in the same manner regardless of the setting (in this case, HOPDs and freestanding radiation therapy centers) and paid prospectively based on episodes of care. While payment amounts may vary across RO participants, the calculation of how much each RO participant would be paid for the PC and TC of the episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Applying the Hospital OQR Program payment reduction would undermine our goal of site-neutral payments under the RO Model because it could affect HOPDs, but not freestanding radiation therapy centers, creating additional variables that could complicate a neutral comparison. If the requirement to apply the Hospital OQR Program payment

reduction were not waived, the participant-specific technical episode payments made with respect to services furnished by RO participants in HOPDs that are billed under the technical RO Model-specific HCPCS codes may be decreased due to the Hospital OQR Program payment reduction. Meanwhile, the Hospital OQR Program payment reduction would not apply to participating freestanding radiation therapy centers, which are paid under the PFS not OPPS. We believe the potential differences between participant-specific technical episode payments made for services furnished in HOPDs and those made under the PFS that would be caused by the application of the Hospital OQR Program payment reduction would be problematic for the RO Model test by creating potentially misaligned incentives for RO participants. The Hospital OQR Program payment reduction may interfere with how the RO Model pricing methodology has been conceptualized and therefore impact the model evaluation by introducing additional variability into RO participants' payments, thereby making it harder to discern whether the episode-based bundled payment approach is successful.

For these reasons, we believe that it would be necessary to waive the requirement to apply the Hospital OQR Program payment reduction under section 1833(t)(17)(A)(i) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services billed under the technical RO Model-specific HCPCS codes. As such, we are proposing to waive application of the 2.0 percentage point reduction under section 1833(t) (17) of the Act for only those APCs that include only RO Model-specific HCPCS codes during the model performance period. We seek comment on our proposal to waive application of the Hospital OQR Program 2.0 percentage point reduction through use of the reporting ratio for APCs that include the new HCPCS codes that are created for the RO Model during the model performance period.

b. Proposed Waiver of the Requirement To Apply the MIPS Payment Adjustment Factors to Certain RO Model Payments

Under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e), the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) generally apply to the amount otherwise paid under Medicare Part B with respect to covered professional services furnished by a MIPS eligible clinician during the applicable MIPS payment year. We propose to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services furnished by a MIPS eligible clinician and billed under the professional RO Model-specific HCPCS codes (as identified in Table 2) because we believe that it would be necessary solely for purposes of testing the RO Model.

The RO Model is a test of a site-neutral pricing methodology, where payment rates are calculated in the same manner regardless of the setting and paid prospectively based on episodes of care. While payment amounts may vary across RO participants, the calculation of how much each RO participant would be paid for the PC and TC of the episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Applying the MIPS payment adjustment factors would undermine our goal of site-neutral payments under the RO Model.

If the requirement to apply the MIPS payment adjustment factors were not waived, the participant-specific technical episode payments made with respect to services furnished by MIPS eligible clinicians in freestanding radiation therapy centers that are billed under the professional RO Model-specific HCPCS codes may be increased or decreased due to the MIPS payment adjustment factors. In contrast, the MIPS payment adjustment factors would not apply to payments of claims processed under the OPPS, and as a result, would not apply to the participant-specific technical episode payments made to participating HOPDs. We believe the potential differences between participant-specific technical episode payments made for services furnished in freestanding radiation therapy centers and those made under the OPPS that would be caused by the application of the MIPS payment adjustment factors would be problematic for the RO Model test by creating potentially misaligned incentives for RO participants as well as other challenges for the Model evaluation. We believe that without this waiver, model participants may be incentivized to change their behavior and steer beneficiaries towards freestanding radiation therapy centers if they expect the MIPS payment adjustment factors would be positive, and away from freestanding radiation therapy centers if they expect the MIPS payment adjustment factors would be negative.

RO participants that bill for services under the professional RO Model-specific HCPCS codes would be subject to payment adjustments under the Model based on quality performance through the quality withhold. The MIPS payment adjustment factors are determined in part based on a MIPS eligible clinician's performance on quality measures for a performance period. We believe subjecting a RO participant to payment consequences under MIPS and the Model for potentially the same quality performance could have unintended consequences. The MIPS payment adjustment factors may interfere with how the RO Model pricing methodology has been conceptualized and therefore impact the model evaluation by introducing additional variability into RO participants' payments thereby making it harder to discern whether the episode-based bundled payment approach is successful. For these reasons, we believe that it would be necessary to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services billed under the professional RO Model-specific HCPCS codes.

c. Proposed Waiver of Requirement To Include Technical Component Payments in Calculation of the APM Incentive Payment Amount

We believe that it is necessary for purposes of testing the RO Model to exclude payments for the technical RO Model-specific HCPCS codes (to the extent they might be considered payments for covered professional services as defined in section 1848(k)(3)(A) of the Act) from the ''estimated aggregate payment amounts for covered professional services'' used to calculate the APM Incentive Payment amount under 42 CFR 414.1450(b). The regulation at 42 CFR 414.1450(b) establishes the APM Incentive Payment Amount; we specifically believe it is necessary to exclude the technical RO Model-specific HCPCS codes from the calculation of estimated aggregate payments for covered professional services as defined in 42 CFR 414.1450(b)(1). The RO Model HCPCS codes are split into a professional component and a technical component to reflect the two types of services provided in the Model by the three different RO participant types, PGPs, HOPDs, and freestanding radiation therapy centers, across different service sites. RO participants would bill the

Model-specific HCPCS codes that are relevant to their RO participant type.

We believe this waiver is necessary because, under 42 CFR 414.1450, the APM Incentive Payment amount for an eligible clinician who is a QP is equal to 5 percent of his/her prior year estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act. The technical RO Model-specific HCPCS codes include the codes that we have developed to bill the services on the included RT services list that are considered ''technical'' (those that represent the cost of the equipment, supplies and personnel used to perform the procedure).

If the requirement to include payments for the technical RO Model-specific HCPCS codes in the calculation of the APM Incentive Payment amount were not waived, PGPs furnishing RT services in freestanding radiation therapy centers (which are paid under the PFS) participating in the Model would have technical RT services included in the calculation of the APM Incentive Payment amount, but PGPs furnishing RT services in HOPDs (which are paid under OPPS) participating in the Model would not have technical RT services included in the calculation of the APM Incentive Payment amount. We believe these potential differences between participant-specific technical episode payments processed and made under the PFS and those made under the OPPS would be problematic for the Model test by creating potentially misaligned incentives between and among RO participants, as well as other challenges for the Model evaluation. Specifically, we believe that, without this waiver, Dual participants may change their billing behavior by shifting the setting in which they furnish RT services from HOPDs to freestanding radiation therapy centers in order to increase the amount of participant-specific technical episode payments, producing unwarranted increases in their APM Incentive Payment amount. We believe this would prejudice the model testing of site neutral payments as well as potentially interfere with the Model's design to incentivize participants to preserve or improve quality by tying performance to incentive payments if participant behavior is focused on maximizing the APM Incentive Payment.

For these reasons, we believe that it would be necessary to waive the requirements of 42 CFR 414.1450(b) to the extent they would require inclusion of the technical RO Model-specific HCPCS codes as covered professional services when calculating the APM Incentive Payment amount.

d. Proposed General Payment Waivers

We believe that it is necessary for purposes of testing the RO Model to waive requirements of certain sections of the Act, specifically with regard to how payments are made, in order to allow the RO Model's prospective episode payment to be fully tested. Therefore, we propose to waive:

- Section 1848(a)(1) of the Act that requires payment for physicians' services to be determined under the PFS to allow the professional and technical component payments for RT services to be made as set forth in the RO Model. We believe that waiving section 1848(a)(1) of the Act would be necessary because otherwise the proposed RO Model payments would be set by the PFS;
- Section 1833(t)(1)(A) of the Act that requires payment for outpatient department (OPD) services to be determined under the OPPS to allow the payments for technical component services to be paid as set forth in the RO Model because otherwise the proposed participant-specific technical episode payment would be set by the OPPS (we note that the waiver of OPPS payment would be limited to RT services under the RO Model); and
- Section 1833(t)(16)(D) of the Act regarding payment for stereotactic radiosurgery (a type of RT covered by the RO Model) to allow the payments for technical component services to be paid as set forth in the RO Model because RO Model payment amounts would be modality agnostic and episodic such that all treatments and duration of treatment for this cancer type are paid the same amount.

We propose to waive these requirements because these statutory provisions establish the current Medicare FFS payment methodology. Without waiving these specific provisions of the Act, we would not be able to fully test whether the prospective episode pricing methodology tested under the RO Model (as described in section III.C.6) is effective at reducing program expenditures while preserving or enhancing the quality of care. Specifically, as proposed, the RO Model would test whether adjusting the current fee-for-service payments for RT services to a prospective episode-based payment model would incentivize physicians to deliver higher-value RT care. Without waiving the requirements of statutory provisions that currently determine payments for RT services, payment for RT services would be made using the current FFS payment methodology and not the pricing methodology we are testing through the Model.

e. Proposed Waiver of Appeals Requirements

We believe that it is necessary for purposes of testing the RO Model to waive section 1869 of the Act specific to claims appeals to the extent otherwise applicable. We propose to implement this waiver so that RO participants may utilize the proposed timely error and reconsideration request process specific to the RO Model as proposed in section III.C.12 of this proposed rule to review potential RO Model reconciliation errors. We would note that, if RO participants have general Medicare claims issues they wish to appeal (Medicare claims issues experienced by the RO participant that occur outside the scope of the RO Model, but during their participation in the RO Model), then the RO participants should continue to use the standard CMS claims appeals procedures under section 1869 of the Act.

We propose to implement this waiver because the proposed pricing methodology for the RO Model is unique and as such we have developed and proposed a separate timely error notice and reconsideration request process that RO participants would use in lieu of the claims appeals process under section 1869 of the Act.

In section III.C.12 of this proposal, we propose a process for RO participants to contest the calculation of their reconciliation payment amounts, the calculation of their reconciliation recoupment amounts, and the calculation of their AQS. Reconciliation payment amount means a payment made by CMS to a RO participant as determined in accordance with § 512.285. This process would ensure that individuals involved in adjudicating these timely error notices and reconsideration requests on these issues would be familiar with the payment model being implemented and would ensure that these issues are resolved in an efficient manner by individuals with knowledge of the payment model.

Our proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869. We note, in the specific circumstance wherein a provider acts on behalf of the beneficiary in a claims appeal, section 1869 applies. We only propose to waive the right of RO participants to avail themselves of the claims appeals process under section 1869 to the extent otherwise applicable.

f. Proposed Waiver of Amendments Made by Section 603 of the Bipartisan Budget Act of 2015

We believe that it is necessary for purposes of testing the RO Model to waive application of the PFS relativity adjuster which applies to payments under the PFS for ''non-excepted'' items and services identified by Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), which amended section 1833(t)(1)(B)(v) of the Act and added paragraph (t)(21) to the Social Security Act. Sections 1833(t)(1)(B)(v) and (t)(21) of the Act exclude certain items and services furnished by certain off-campus provider-based departments (non-excepted off-campus provider-based departments (PBDs)) from the definition of covered outpatient department services for purposes of OPPS payment, and direct payment for those services to be made ''under the applicable payment system'' beginning January 1, 2017. We established the PFS as the ''applicable payment system'' for most non-excepted items and services furnished in non-excepted off-campus PBDs (81 FR 79699) and, in order to facilitate payment under the PFS, we apply a PFS relativity adjuster that is currently set at 40 percent of the OPPS rate (82 FR 53027). We also require OPDs to use the modifier ''PN'' on applicable OPPS claim lines to identify non-excepted items and services furnished in non-excepted off-campus PBDs. The modifier triggers application of the PFS relativity adjuster in CMS' claims processing systems.

Under the RO Model, we propose to waive requirements under section 1833(t)(1)(B)(v) and (t)(21) of the Act for all RO Model-specific payments to applicable OPDs. If a non-excepted off-campus PBD were to participate in the RO Model, it would be required to submit RO Model claims consistent with our professional and technical billing proposals in III.C.7. In addition, we would not apply the PFS relativity adjuster to the RO Model payment and would instead pay them in the same manner as other RO Model participants because the RO Model pricing methodology's design as described in Section III.C.6.c sets site-neutral national base rates, and adding the PFS relativity adjuster to the RO Model payment for RO participants that are non-excepted off-campus PBDs would disrupt this approach and introduce a payment differential. We believe this waiver is necessary to allow for consistent model evaluation and ensure site neutrality in RO Model payments, which is a key feature of the RO Model.

We invite public comments on our proposed payment waivers.

11. Proposed Reconciliation Process

We propose to conduct an annual reconciliation for each RO participant after each PY to reconcile payments due to the RO participant with payments owed to CMS due to the withhold policies discussed in section III.C.6.g. The annual reconciliation would occur in August following a PY in order to allow time for claims run-out, data collection, reporting, and calculating results.[61] For example, the annual reconciliation for PY1 would apply to episodes initiated January 1, 2020 (or April 1, 2020) through December 31, 2020, and the annual reconciliation for PY1 would occur in August of 2021. We believe that an annual reconciliation is appropriate because incomplete episodes and duplicate RT services as described in section III.C.6.a may result in additional payment owed to a RO participant or owed to CMS for RT services furnished to a RO beneficiary in those cases.

a. Proposed True-Up Process

We propose to conduct an annual true-up of reconciliation for each PY, which would mean the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out. More specifically, we would true-up the PY1 reconciliation approximately one year after the initial reconciliation results were calculated. This would align the PY2 reconciliation of the following year with the PY1 true-up, thereby allowing for a full claims run-out, and reducing potential confusion for RO participants. We would follow the same process each performance year. We would true-up the PY1 reconciliation approximately one year after the initial reconciliation proposed in § 512.285.section III.C.11. As a result, we would conduct a true-up of PY1 in August 2022, a true-up of PY2 in August 2023, and so forth.

We invite public comments on our proposed true-up process.

b. Proposed Reconciliation Amount Calculation

To calculate a reconciliation payment amount either owed to a RO participant by CMS or a reconciliation repayment amount owed by CMS to a RO participant, we propose the following process:

- Calculate the incorrect payment reconciliation amount: Sum all money the RO participant owes CMS due to incomplete episodes and duplicate services, and subtract the amount from the incorrect payment withhold amount (that is, the cumulative withhold of 2 percent on episode payment amounts for all episodes furnished during that PY by that RO participant). This would determine the amount owed to CMS by the RO participant based on total payments made to the RO participant for incomplete episodes and duplicate RT services for a given PY, if applicable. A RO participant would receive the full incorrect payment withhold amount if it had no duplicate RT services or incomplete episodes (as explained in section III.C.6.g). In instances where there are duplicate RT services or incomplete episodes, the RO participant would owe a repayment amount to CMS if the amount of all duplicate RT services and incomplete episodes exceeds the incorrect payment withhold amount.
- For Professional participants during the Model's performance period: If the RO participant is a Professional participant, then we would add the Professional participant's incomplete episode reconciliation amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the participant's AQS (as a percentage) against the total two-percentage point maximum amount as described in section III.C.8.f(2).
- For Technical participants in PY1 and PY2: If the RO participant is a Technical participant then the Technical participant's reconciliation amount would be equal to the incomplete episode reconciliation amount. There would be no further additions or subtractions.
- For Technical participants in PY3, PY4, and PY5: We would add the Technical participant's incomplete episode reconciliation amount to the patient experience reconciliation amount, proposed in section III.C.6.g(3). Technical participants and Dual participants could earn up to the full amount of the patient experience withhold (1 percent of the technical episode payment amounts) for a given performance year based on their results from the patient-reported CAHPS® Cancer Care Radiation Therapy Survey.
- For Dual participants in PY1 and PY2: We would add the Dual participant's incorrect payment reconciliation amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the Dual participant's AQS (in percentage terms) against the total two-percentage point

[61] Claims run-out is the period of time that CMS allows for the timely submission of claims by providers and suppliers before reconciliation.

maximum withhold amount as described in section III.C.8.f(2).

- For Dual participants in PY3, PY4, and PY5: We would add the Dual participant's incorrect payment reconciliation amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the participant's AQS (in percentage terms) against the total two-percentage point maximum withhold amount as described in section III.C.8.f(2). Then, we would add the Dual participant's patient experience reconciliation amount to this total.

The geographic adjustment and the 2 percent adjustment for sequestration would be applied to the incorrect payment withhold, quality withhold, and patient experience withhold amounts during the reconciliation process. Beneficiary coinsurance would be waived for the reconciliation payment and repayment amounts.

We invite public comment on our proposal on calculating reconciliation amounts.

Table 10 represents an example reconciliation for a Professional participant. The numbers listed in the table are illustrative only. In this example, the incorrect payment withhold amount for this Professional participant is $6,000 or 2 percent of $300,000 (the total payments for this participant after the trend factor, adjustments, and discount factor have been applied). The Professional participant owes CMS $3,000 for duplicate payments due to claims submitted on behalf of beneficiaries who received RT services by another provider or supplier during their episode. Lastly, the Professional participant owes CMS $1,500 for cases of incomplete episodes whereby the PC of the episode was billed and due to death or other reason, the TC was not billed by the time of reconciliation. In this example, the payments for duplicate RT services and incomplete episodes would be subtracted from the incorrect payment withhold amount to render $1,500 due to the participant from CMS for the incorrect payment reconciliation amount (a). This amount is then added to the quality reconciliation amount (b). The quality withhold amount for this participant is also $6,000 or 2 percent of $300,000. This participant's performance on the AQS entitles them to 85 percent of the quality withhold, and, therefore, when the quality reconciliation amount (b) is added to the incorrect payment withhold amount (a), and a total payment of $6,600 total reconciliation payment (c) is due to the participant from CMS for that performance year. We note that this example does not include the geographic adjustment or the 2 percent adjustment for sequestration.

TABLE 10: EXAMPLE RECONCILIATION CALCULATION FOR A PROFESSIONAL PARTICIPANT

Professional participant	Formula	Example 1
Incorrect Payment Reconciliation Amount (a)		
Incorrect Payment Withhold Amount (a_1)	a_1	$6,000
Duplicate RT Services Adjustment (a_2)	a_2	($3,000)
Incomplete Billing Adjustment (a_3)	a_4	($1,500)
Total ($a_1 + a_2 + a_3$)	$a = a_1 + a_2 + a_3$	$1500
Quality Reconciliation Amount (b)		
Quality Withhold (b_1)	b_1	$6,000
AQS (b_2)	b_2	0.85
Product ($b_1 * b_2$)	$b = b_1 * b_2$	$5,100
Total Payment/Recoupment (c)	$c = a + b$	$6,600

12. Proposed Timely Error Notice and Reconsideration Request Processes

We believe it is necessary to implement timely error notice and reconsideration request processes under which RO participants may dispute suspected errors in the calculation of their reconciliation payment amount or repayment amount (proposed in section III.C.11), or AQS (proposed in section III.C.8.f(1)) as reflected on a RO reconciliation report that has not been deemed final. Therefore, we are proposing a policy that would permit RO participants to contest errors found in the RO reconciliation report, but not the RO Model pricing methodology or AQS methodology. We note that, if RO participants have Medicare FFS claims or decisions they wish to appeal (that is, Medicare FFS issues experienced by the RO participant that occur outside the scope of the RO Model but during their participation in the RO Model), then the RO participants should continue to use the standard CMS procedures through their Medicare Administrative Contractor. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims decisions made by CMS.

However, we propose to waive the requirements of section 1869 of the Act specific to claims appeals as necessary solely for purposes of testing the RO Model. Specifically, we believe it is necessary to establish a means for RO participants to dispute suspected errors in the calculation of their reconciliation payment amount, repayment amount, or AQS. Having RO participants utilize the standard claims appeals process under section 1869 of the Act to appeal the calculation of their reconciliation payment amount, repayment amount, or AQS would not lead to timely resolution of disputes because MACs and other CMS officials will not have access to beneficiary attribution data, and the standard claims appeals process hierarchy would not engage the Innovation Center and its contractors until late in the process. Accordingly,

we propose a two-level process for RO participants to request reconsideration of determinations related to calculation of their reconciliation payment, recoupment amount, or AQS under the RO Model. We propose the first level to be a timely error notice process and the second level to be reconsideration review process, as subsequently discussed. The processes proposed here are based on the processes implemented under certain current models being tested by the Innovation Center.

We propose that only RO participants may utilize either the first or second level of the reconsideration process, unless otherwise stated in other sections of this proposed subpart. We believe that only RO participants should be able to utilize the proposed process because non-participants will not receive calculation of a reconciliation payment amount, repayment amount, or AQS, and will generally have access to the section 1869 claims appeals processes to appeal the payments they receive under the Medicare program.

1. Timely Error Notice

In some models currently being tested by the Innovation Center, CMS provides model participants with a courtesy copy of the settlement report for their review, allowing them to dispute suspected calculation errors in that report before the payment determination is deemed final. Other models currently being tested by the Innovation Center make model-specific payments in response to claims or on the basis of model beneficiary attribution that are similarly subject to a model-specific process for resolving disputes. In some models currently being tested by the Innovation Center, these reconsideration processes involve two levels of review.

Building off of these existing processes, we propose that the first level of the proposed reconsideration process would be a timely error notice. Specifically, we are proposing that RO participants could provide written notice to CMS of a suspected error in the calculation of their reconciliation payment amount, repayment amount, or AQS for which a determination has not yet been deemed to be final under the terms of this proposed part. The RO participant shall have 30 days from the date the RO reconciliation report is issued to provide their timely error notice. This would be subject to the limitations on administrative and judicial review as previously described. Specifically, a RO participant could not use the timely error notice process to dispute a determination that is precluded from administrative and judicial review under section 1115A(d)(2) of the Act and proposed § 512.290. We propose that this written notice must be submitted in a form and manner specified by CMS. Unless the RO participant provides such notice, the RO participant's reconciliation payment amount, repayment amount, or AQS would be deemed final after 30 days, and CMS would proceed with payment or repayment, as applicable. If CMS receives a timely notice of an error, we propose that CMS would respond in writing within 30 days to either confirm that there was a calculation error or to verify that the calculation is correct. CMS would reserve the right to an extension upon written notice to the RO participant. We propose to codify this timely error notice policy at § 512.290(a).

2. Reconsideration Review

We propose that the second level of the proposed reconsideration process would permit RO participants to dispute CMS's response to the RO participant's identification of errors in the timely error notice, by requesting a reconsideration review by a CMS reconsideration official. As is the case for many models currently being tested by the Innovation Center, we propose that the CMS reconsideration official would be a designee of CMS who is authorized to receive such requests who was not involved in the responding to the RO participant's timely error notice. We are proposing that, to be considered, the reconsideration review request must be submitted to CMS within 10 days of the issue date of CMS' written response to the timely error notice. We propose the reconsideration review request would be submitted in a form and manner specified by CMS.

As there would not otherwise be a timely error notice response for the reconsideration official to review, we are proposing that in order to access the reconsideration review process, a RO participant must have timely submitted a timely error notice to CMS in the form and manner specified by CMS, and this timely error notice must not have been precluded from administrative and judicial review. Specifically, where the RO participant does not timely submit a timely error notice with respect to a particular reconciliation payment amount, repayment, recoupment amount, or AQS, we propose the reconsideration review process would not be available to the RO participant with regard to the RO participant's reconciliation payment amount; the calculation of the RO participant's repayment amount; or the calculation of the RO participant's AQS.

If the RO participant did timely submit a timely error notice and the RO participant is dissatisfied with CMS's response to the timely error notice, the RO participant would be permitted to request reconsideration review by a CMS reconsideration review official. To be considered, we propose that the reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment amount, repayment, recoupment amount, or AQS in accordance with the terms of the RO Model.

We propose that the reconsideration review would be an on-the-record review (a review of the memoranda or briefs and evidence only) conducted by a CMS reconsideration official. The CMS reconsideration official would make reasonable efforts to notify the RO participant and CMS in writing within 15 days of receiving the RO participant's reconsideration review request of the following: The issues in dispute, the briefing schedule, and the review procedures. The briefing schedule and review procedures would lay out the timing for the RO participant and CMS to submit their position papers and any other documents in support of their position papers; the review procedures would lay out the procedures the reconsideration official will utilize when reviewing the reconsideration review request. The CMS reconsideration official would make all reasonable efforts to complete the on-the-record review of all the documents submitted by the RO participant and issue a written determination within 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule. As this is the final step of the Innovation Center administrative dispute resolution process, we propose that the determination made by the CMS reconsideration official would be final and binding. This proposed reconsideration review process is consistent with other resolution processes used throughout the agency. We propose to codify this reconsideration review process at § 512.290(b).

We invite public comment on these proposed provisions regarding the proposed timely error notice and reconsideration review processes.

13. Proposed Data Sharing

CMS has experience with a range of efforts designed to improve care coordination and the quality of care,

and decrease the cost of care for beneficiaries, including models tested under section 1115A, most of which make certain types of data available upon request to model participants. Based on the design elements of each model, the Innovation Center may offer participants the opportunity to request different types of data, so that they can redesign their care pathways to preserve or improve quality and coordinate care for model beneficiaries. Furthermore, as previously described, we believe it is necessary for the Innovation Center to require certain data to be reported by model participants to CMS in order to evaluate and monitor the proposed model, including the model participant's participation in the proposed model, which could then also be used to inform the public and other model participants regarding the impact of the proposed model on both program spending and the quality of care.

a. Data Privacy Compliance

In proposed § 512.275(a), we propose that, as a condition of their receipt of patient-identifiable data from CMS for purposes of the RO Model, RO participants must comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the RO Model and the terms of any agreement entered into by the RO participant and CMS as a condition of the RO participant receiving such data. These laws include, without limitation, the standards for the privacy of individually identifiable health information and the security standards for the protection of electronic protected health information under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). Additionally, we are proposing that RO participants would be required to contractually bind all downstream recipients of CMS data to comply with all laws pertaining to any patient-identifiable data requested from CMS and the terms of any agreement that the RO participant enters into with CMS as a condition of receiving the data under the RO Model, as a condition of the downstream recipient's receipt of the data from the RO participant and their maintenance thereof. We believe requiring RO participants to bind their downstream recipients in writing to comply with applicable law and requirements is necessary to protect the individually identifiable health information data that may be shared with RO participants by CMS for care redesign and care coordination purposes.

b. RO Participant Public Release of Patient De-Identified Information

We are not proposing to restrict RO participants' ability to publicly release patient de-identified information that references the RO participant's participation in the RO Model. Information that RO participants may publicly release about their participation in the RO Model may include, but is not limited to, press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials describing the RO participant's participation and patient results in the RO Model that have been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b). In order to ensure external stakeholders understand that information the RO participant releases represents their own content and opinion, and does not reflect the input or opinions of CMS, we propose to require the RO participant to include a disclaimer on the first page of any such publicly released document, the content of which materially and substantially references or relies upon the RO participant's participation in the RO Model. We propose to utilize the same disclaimer for public release of information by the RO participant that we propose to codify at § 512.120(c)(2) for purposes of descriptive model materials and activities: ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.'' We are proposing to require the use of this disclaimer so that the public, and RO beneficiaries in particular, are not misled into believing that RO participants are speaking on behalf of the agency.

c. Proposed Data Submitted by RO Participants

In addition to the quality measures and clinical data described in section III.C.8, we propose that RO participants supply and/or confirm a limited amount of summary information to CMS. This information includes the RO participant's TIN in the case of a freestanding radiation therapy center and PGP, or CCN in the case of a HOPD. We would require RO participants to supply and/or confirm the NPIs for the physicians who bill for RT services using the applicable TINs. RO participants may be required to provide information on the number of Medicare and non-Medicare patients treated with radiation during their participation in the Model. We propose to require RO participants' submission of additional administrative data upon a request from CMS, such as the RO participant's costs to provide care (such as the acquisition cost of a linear accelerator) and how frequently the radiation machine is used on an average day; current EHR vendor(s); and accreditation status. We propose to do this through annual web-based surveys. The data requested for use under the RO Model will be used to better understand participants' office activities, benchmarks, and track participant compliance.

d. Proposed Data Provided to RO Participants

Thirty (30) days prior to the start of each PY, we propose to provide RO participants with updated participant-specific professional episode payment and technical episode payment amounts (for example, episode price files) for each included cancer type. RO participants, to the extent allowed by HIPAA and other applicable law, could reuse individually identifiable claims data that they request from CMS for care coordination or quality improvement work and in their assessment of CMS' calculation of their participant-specific episode payment amounts and/or amounts included in the reconciliation calculations used to determine the reconciliation payment amount or recoupment amount, as applicable. To seek such care coordination and quality improvement data RO participants should use a Participant Data Request and Attestation (DRA) form, which will be available on the RO Model website. Throughout the model performance period, RO participants may request to continue to receive these data until the final reconciliation and final true-up process has been completed if they continue to use such data for care coordination and quality improvement purposes. At the conclusion of this process, the RO participant would be required to maintain or destroy all data in its possession in accordance with the DRA and applicable law.

We further propose that the RO participant may reuse original or derivative data without prior written authorization from us for clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation, but shall not disseminate individually identifiable original or derived information from the files specified in the Model DRA to

anyone who is not a HIPAA Covered Entity Participant or individual practitioner in a treatment relationship with the subject Model beneficiary; a HIPAA Business Associate of such a Covered Entity Participant or individual practitioner; the participant's business associate, where that participant is itself a HIPAA Covered Entity; the participant's sub-business associate, which is hired by the RO participant to carry out work on behalf of the Covered Entity Participant or individual practitioners; or a non-participant HIPAA Covered Entity in a treatment relationship with the subject Model beneficiary.

When using or disclosing PHI or personally identifiable information (PII) obtained from files specified in the DRA, the RO participant would be required to make ''reasonable efforts to limit'' the information to the ''minimum necessary'' as defined by 45 CFR 164.500 through 164.534 to accomplish the intended purpose of the use, disclosure or request. The RO participant would be required to further limit its disclosure of such information to what is permitted by applicable law, including the regulations promulgated under the HIPAA and HITECH laws at 45 CFR part 160 and subparts A and E of part 164, and the types of disclosures that the Innovation Center itself would be permitted to make under the ''routine uses'' in the applicable systems of records notices listed in the DRA. We propose that the RO participant may link individually identifiable information specified in the DRA (including directly or indirectly identifiable data) or derivative data to other sources of individually identifiable health information, such as other medical records available to the participant and its individual practitioner. The RO participant would be authorized to disseminate such data that has been linked to other sources of individually identifiable health information provided such data has been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b).

We invite public comment on our proposals related to data sharing for the RO Model.

f. Access To Share Beneficiary Identifiable Data

As discussed earlier in this proposed rule, in advance of each PY and any other time deemed necessary by us, we will offer the RO participant an opportunity to request certain data and reports through a standardized DRA, if appropriate to that RO participant's situation. The data and reports provided to the RO participant in response to a DRA would not include any beneficiary-level claims data regarding utilization of substance use disorder services unless the requestor provides a 42 CFR part 2-compliant authorization from each individual about whom they seek such data. While the proffered DRA form was drafted with the assumption that most RO participants seeking claims data will do so under the HIPAA Privacy Rule provisions governing ''health care operations'' disclosures under 45 CFR 164.506(c)(4), in offering RO participants the opportunity to use that form to request beneficiary-identifiable claims data, we do not represent that the RO participant or any of its individual practitioners has met all applicable HIPAA requirements for requesting data under 45 CFR 164.506(c)(4). The RO participant and its individual practitioners should consult their own counsel to make those determinations prior to requesting data using the DRA form.

Agreeing to the terms of the DRA, the RO participant, at a minimum, would agree to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use of or access to it. The safeguards would be required to provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget (OMB) in OMB Circular No. A–130, Appendix I—Responsibilities for Protecting and Managing Federal Information Resources (available at *https://www.whitehouse.gov/omb/circulars_default*) as well as Federal Information Processing Standard 200 entitled ''Minimum Security Requirements for Federal Information and Information Systems'' (available at *http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf*); and, NIST Special Publication 800–53 ''Recommended Security Controls for Federal Information Systems'' (available at *http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf*). The RO participant would be required to acknowledge that the use of unsecured telecommunications, including insufficiently secured transmissions over the internet, to transmit directly or indirectly identifiable information from the files specified in the DRA or any such derivative data files would be strictly prohibited. Further, the RO participant would be required to agree that the data specified in the DRA would not be physically moved, transmitted, or disclosed in any way from or by the site of the Data Custodian indicated in the DRA without written approval from CMS, unless such movement, transmission, or disclosure is required by a law. At the conclusion of the RO Model and reconciliation process, the RO participant would be required to destroy all data in its possession as agreed upon under the DRA.

14. Proposed Monitoring and Compliance

If finalized, the general provisions relating to monitoring and compliance proposed in section II.I of this rule would apply to the RO Model. Specifically, RO participants would be required to cooperate with the model monitoring and evaluation activities in accordance with § 512.130, comply with the government's the right to audit, inspect, investigate, and evaluate any documents or other evidence regarding implementation of the RO Model under § 512.135(a), and to retain and provide the government with access to records in accordance with §§ 512.135(b) and (c). Additionally, CMS would conduct model monitoring activities with respect to the RO Model in accordance with § 512.150(b). We believe that the general provisions relating to monitoring and compliance are appropriate for the RO Model, because we must closely monitor the implementation and outcomes of the RO Model throughout its duration. The purpose of monitoring would be to ensure that the Model is implemented safely and appropriately; that RO participants comply with the terms and conditions of this rule; and to protect beneficiaries from potential harms that may result from the activities of a RO participant.

Consistent with § 512.150(b), we anticipate that monitoring activities may include documentation requests sent to RO participants and individual practitioners on the individual practitioner list; audits of claims data, quality measures, medical records, and other data from RO participants and clinicians on the individual practitioner list; interviews with members of the staff and leadership of the RO participant and clinicians on the individual practitioner list; interviews with beneficiaries and their caregivers; monitoring quality outcomes; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. We anticipate using the most recent claims data available to track utilization as described in section III.C.7, and beneficiary outcomes under the Model. More specifically, we may track utilization of certain types of treatments,

beneficiary hospitalization and emergency department use, and fractionation (numbers of treatments) against historical treatment patterns for each participant. We believe this type of monitoring is important because as RO participants transition from receiving FFS payment to receiving new (episode-based) payment, we want ensure to the greatest extent possible that the Model is effective and that RO Model beneficiaries continue to receive high-quality and medically appropriate care.

Additionally, we may employ longer-term analytic strategies to confirm our ongoing analyses and detect more subtle or hard-to-determine changes in care delivery and beneficiary outcomes. Some determinations of beneficiary outcomes or changes in treatment delivery patterns may not be able to be built into ongoing claims analytic efforts and may require longer-term study. This work may involve pairing clinical data with claims data to identify specific issues by cancer type.

a. Proposed Monitoring for Utilization/Costs and Quality of Care

We would monitor RO participants for compliance with RO Model requirements. We anticipate monitoring to detect possible attempts to manipulate the system through patient recruitment and billing practices. The pricing methodology requires certain assumptions about patient characteristics, such as diagnoses, age, and stage of disease, based on the historical case mix of the individual participants. It also assigns payments by cancer type. Because of these features, participants could attempt to manipulate patient recruitment in order to maximize revenue (for example, cherry-picking, lemon-dropping, or shifting patients to a site of service for which the participant bills Medicare that is not in a randomly selected CBSA). We anticipate monitoring compliance with RO Model-specific billing guidelines and adherence to current LCDs which provide information about the only reasonable and necessary conditions of coverage allowed. We also intend to monitor patient and provider/supplier characteristics, such as variations in size, profit status, and episode utilization patterns, over time to detect changes that might suggest attempts at such manipulation.

To allow us to conduct this monitoring, RO participants would report data on program activities and beneficiaries consistent with the data collection policies proposed in section III.C.8. These data would be analyzed by CMS or our designee for quality, consistency, and completeness; further information on this analysis will be provided to RO participants in a time and manner specified by CMS prior to collection of this data. We would use existing authority to audit claims and services, to use the QIO to assess for quality issues, to use our authority to investigate allegations of patient harm, and to monitor the impact of the RO Model quality metrics. We may monitor participants to detect issues with beneficiary experience of care, access to care, or quality of care. We may monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns.

We invite public comment on our proposal.

b. Proposed Monitoring for Model Compliance

As explained in section III.C.9, we propose to require all participants to annually attest in a form and manner specified by CMS that they would use CEHRT throughout such PY in a manner sufficient to meet the requirements as set forth in 42 CFR 414.1415(a)(1)(i). In addition, we further propose that each Technical participant and Dual participant would be required to attest annually that it actively participates in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). This attestation would be required to ensure compliance with this RO Model requirement. CMS may change these intervals throughout the Model upon advanced written notice to the RO participants. We propose to codify these RO Model requirements at § 512.220(a)(3). We note that CMS may monitor the accuracy of such attestations and that false attestations would be punishable under applicable federal law.

In addition, we would monitor for compliance with the other RO Model requirements listed in this section through site visits and medical record audits conducted in accordance with § 512.150. We propose to codify at § 512.220(a)(2) to require that all Professional participants and Dual participants document in the medical record that the participant: (i) Has discussed goals of care with each RO beneficiary before initiating treatment and communicated to the RO beneficiary whether the treatment intent is curative or palliative; (ii) adheres to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or document in the medical record the rationale for the departure from these guidelines; (iii) assesses the RO beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses; (iv) assesses the RO beneficiary's performance status as a quantitative measure determined by the physician; (v) sends a treatment summary to each RO beneficiary's referring physician within three months of the end of treatment to coordinate care; (vi) discusses with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and (vii) performs and documents Peer Review (audit and feedback on treatment plans) for 50 percent of new patients in PY1, for 55 percent of new patients in PY2, for 60 percent of new patients in PY3, for 65 percent of new patients in PY4, and for 70 percent of new patients in PY5 preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment.

We invite public comment on this proposal.

c. Proposed Performance Feedback

We propose to provide detailed and actionable information regarding RO participant performance related to the RO Model. We intend to leverage the clinical data to be collected through the model-specific data collection system, quality measure results reported by RO participants, claims data, and compliance monitoring data to provide information to participants on their adherence to evidence-based practice guidelines, quality and patient experience measures, and other quality initiatives. We believe these reports can drive important conversations and support quality improvement progress. The design of and frequency that these reports would be provided to participants would be determined in conjunction with the RO Model implementation and monitoring contractor.

We invite public comment on our proposal.

d. Proposed Remedial Action for Non-Compliance

We refer readers to section II.J of this proposed rule for our proposals regarding remedial and administrative action.

15. Beneficiary Protections

We propose to require Professional participants and Dual participants to notify RO beneficiaries that the RO participant is participating in this RO Model by providing written notice to each RO beneficiary during the RO beneficiary's initial treatment planning

session. We intend to provide a notification template that RO participants may personalize with their contact information and logo, which would explain that the RO participant is participating in the RO Model and would include information regarding RO beneficiary cost-sharing responsibilities and a RO beneficiary's right to refuse having his or her data shared under § 512.225(a)(2). Beneficiaries who do not wish to have their data shared under the Model would be able to notify their respective RO participant; in such cases the RO participant must notify in writing CMS within 30 days of when the beneficiary notifies the RO participant.

We believe it would be important that RO participants provide RO beneficiaries with a standardized, CMS-developed RO beneficiary notice in order to limit the potential for fraud and abuse, including patient steering. We propose that the required RO Model beneficiary notice be exempt from the requirement at § 512.120(c)(2) and in section II.D.3 of this part, which requires that the model participant include a disclaimer statement on all descriptive model materials and activities that ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.'' We believe that such statement should not apply to the proposed RO Model beneficiary notice, because RO participants would be required to use standardized language developed by CMS. We propose these policies at § 512.225(c).

If beneficiaries have any questions or concern with their physicians, we encourage them to telephonically contact the CMS using 1–800–MEDICARE, or their local Beneficiary and Family Centered Care–Quality Improvement Organizations (BFCC–QIOs) (local BFCC–QIO contact information can be located here: *https://qioprogram.org/beneficiary-and-family-centered-care-national-coordinating-center*).

We invite public comment on the proposed beneficiary protections.

16. Proposed Evaluation

An evaluation of the RO Model would be required to be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center.

Our evaluation would focus primarily on understanding how successful the Model is in achieving improved quality and reduced expenditures as evidenced by changes in RT utilization patterns (including the number of fractions and types of RT), RT costs for Medicare FFS beneficiaries in the RO Model (including Medicare-Medicaid dually eligible beneficiaries), changes in utilization and costs with other services that may be affected as a result of the RO Model (such as emergency department services, imaging, prescription drugs, and inpatient hospital care), performance on clinical care process measures (such as adhering to evidence-based guidelines), patient experience of care, and provider experience of care. The evaluation would inform the Secretary and policymakers about the impact of the model relative to the current Medicare fee structure for RT services, assessing the impacts on beneficiaries, providers, markets, and the Medicare program. The evaluation would take into account other models and any changes in Medicare payment policy during the model performance period.

In addition to assessing the impact of the Model in achieving improved quality and reduced Medicare expenditures, the evaluation is likely to address questions that include (but would not be limited to): Did utilization patterns with respect to modality or number of fractions per episode change under the model? If the Model results in lower Medicare expenditures, what aspects of the Model reduced spending and were those changes different across subgroups of beneficiaries or related to observable geographic or socio-economic factors? Did any observed differences in concordance with evidence-based guidelines vary by cancer type or by treatment modality? Did patient experience of care improve? Did the Model affect access to RT or other services overall or for vulnerable populations? Were there design and implementation issues with the RO Model? What changes did participating radiation oncologists and other RO care team members experience under the Model? Did any unintended consequences of the Model emerge? Was there any observable overlap between the RO Model and other CMMI models or CMS/non-CMS initiatives and how could they impact the evaluation findings?

CMS anticipates that the evaluation would include a difference-in-differences [62] or similar analytic approach to estimate model effects. Where it is available, baseline data for the participants would be obtained for at least one year prior to model implementation. Data would also be collected during model implementation for both participant and comparison groups. The evaluation would control for patient differences and other factors that directly and indirectly affect the RO Model impact estimate, including demographics, comorbidities, program eligibility, and other factors. Data to control for patient differences would be obtained primarily from claims and patient surveys.

The evaluation would use a multilevel approach. We would conduct analyses at the CBSA-level, participant-level, and the beneficiary-level. The CBSAs and RT providers and RT suppliers contained within selected CBSA geographic areas, as discussed in section III.C.3.d, would have been randomly assigned for the duration of the evaluation, allowing us to use scientifically rigorous methods for evaluating the effect of the Model.

We refer readers to section II.E of this proposed rule for our proposed policy on RO participant cooperation with the RO Model's evaluation and monitoring policies. We invite public comment on our proposed approach related to the evaluation of the RO Model.

17. Termination of the RO Model

The proposed general provisions relating to termination of the Model by CMS proposed in section II.J of this rule would apply to the RO Model.

18. Potential Overlap With Other Models Tested Under Section 1115A Authority and CMS Programs

a. Overview

The RO Model would leverage existing Innovation Center work and initiatives, broadening that experience to RT providers and RT suppliers, a professional population that is not currently the focus of other models tested by the Innovation Center. We believe that the RO Model would be compatible with other CMS models and

[62] Difference-in-difference is a statistical technique that compares the intervention (in this case, the RO participant) and comparison (in this case, the Comparison group) groups during the period before the RO Model goes into effect (pre-intervention) and the period during and after the RO Model goes into effect (post-intervention) and uses the difference between intervention and comparison in both periods to estimate the effect of the intervention. A comparison group that is similar to the intervention group is used to help measure the size of the intervention effect by providing a comparison (or 'counterfactual') to what would have happened to the intervention group had the intervention not occurred. This helps the evaluation distinguish between changes occurring for reasons unrelated to the model when estimating the changes that occurred because of the model.

programs that also provide health care entities with opportunities to improve care and reduce spending. We expect that there would be situations where a Medicare beneficiary in a RO Model episode would also be assigned to, or engage with, another payment model being tested by CMS. Overlap could also occur among providers and suppliers at the individual or organization level; for example, a physician or organization could be participating in multiple models tested by the Innovation Center. We believe that the RO Model would be compatible with other CMS initiatives that provide opportunities to improve care and reduce spending, especially population-based models, though we recognize the design of some models being tested by the Innovation Center under its section 1115A authority could create unforeseen challenges at the organization, clinician, or beneficiary level. Currently, we do not envision that the prospective episode payments made under the RO Model would need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Medicare Shared Savings Program (Shared Savings Program) under section 1899 of the Act. If, in the future, we determine that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking.

b. Accountable Care Organizations (ACOs)

We believe there would be potential overlap between the proposed RO Model and ACO initiatives. ACO initiatives include a shared savings component. As a result, providers and suppliers that participate in an ACO are generally prohibited from participating in other CMS models or initiatives involving shared savings.[63] We believe there would be potential for overlap between the RO Model and ACO initiatives but, because the RO Model is an episode-based payment initiative, providers and suppliers participating in the RO Model would not be precluded from also participating in an ACO initiative. Specifically, we believe overlap could likely occur in two instances: (1) The same provider or supplier participates in both a Medicare ACO initiative and the RO Model; or (2) a beneficiary that is aligned to an ACO participating in a Medicare ACO initiative receives care at a radiation oncology provider or supplier outside the ACO that is participating in the RO Model.

While shared savings payments made under an ACO initiative have the potential to overlap with discounts and withholds in the RO Model, it is difficult to determine the level of potential overlap at this time. It is also difficult to determine how many aligned ACO beneficiaries would require RT services or if those beneficiaries would seek care from a RO participant. Given that the RO Model is expected to reduce Medicare spending in aggregate, we anticipate that in most cases payments under the RO Model would be less than what Medicare would have paid outside the Model. It is possible, however, for RO participants to receive higher Medicare payments under the Model than they did historically, for example, if they have certain experience adjustments. While we expect overall payments for RT services to be lower than they would be absent the Model, we want to ensure that a significant proportion of the RO Model discounts, which represent Medicare savings, would not be paid out as shared savings.

Due to these factors, we intend to continue to review the potential overlap with the ACO initiatives as the RO Model is launched. If substantial overlap occurs, we would consider adjusting the RO Model payments through future rulemaking to ensure Medicare retains the discount amount. ACO initiatives could also consider accounting for RO Model overlap in their own reconciliation calculations. Any changes to these calculations that might be necessary due to the overlap with the RO Model would be made using the applicable ACO initiative procedures.

c. Oncology Care Model (OCM)

OCM seeks to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. OCM episodes encompass a 6-month period that is triggered by the receipt of chemotherapy and incorporate all aspects of care during that timeframe, including RT services. Because OCM and the RO Model both involve care for patients with a cancer diagnosis who receive RT services, we expect that there would be beneficiaries who would be in both OCM episodes and the RO Model episodes.

Under OCM, physician practices may receive a performance-based payment (PBP) for episodes of care surrounding chemotherapy administration to cancer patients. OCM is an episode payment model that incentivizes care coordination and management and seeks to improve care and reduce costs for cancer patients receiving chemotherapy. Given the significant cost of RT, OCM episodes that include RT services receive a risk adjustment when calculating episode benchmarks, with the goal of mitigating incentives to shift these services outside the episode (for example, by delaying the provision of RT services until after the 6-month episode ends).

Practices participating in OCM receive a monthly payment per OCM beneficiary to support enhanced services such as patient navigation and care planning. Practices may also earn a PBP for reductions in the total cost of care compared to episodes' target amount, with the amount of PBP being adjusted by the practice's performance on quality measures. OCM offers participating practices the option of requesting a two-sided risk arrangement, in which episode expenditures that exceed the target amount or the target amount plus the minimum threshold for OCM recoupment (depending on the specific two-sided risk arrangement requested) would be recouped by CMS from the practice. OCM requires participating practices who have not earned a PBP by the initial reconciliation of the model's fourth performance period to move to a two-sided risk arrangement or terminate their participation in the model.

As proposed in section III.C.7, the RO Model would include prospective episode payments for RT services furnished during a 90-day episode of care. The RO Model is not a total cost of care model and only includes RT services in the episode payment. Since the RO Model makes prospective payments for only the RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in OCM.

Conversely, OCM is a total cost of care model so any changes in the cost of RT services during an OCM episode could affect OCM episode expenditures, and therefore, have the potential to affect a participating practice's PBP or recoupment. When the RO Model episode occurs completely before or completely after the OCM episode, then the RT services that are part of that RO Model episode would not be included in the OCM episode, and the OCM reconciliation calculations would be unaffected. If an entire RO Model episode (90-days of RT services) occurs completely during a 6-month OCM episode, then the associated RO payments for RT services would be

[63] The statutory limitation under § 1899(b)(4)(A) of the Social Security Act, only applies to providers and suppliers that participate in Shared Savings Program ACOs. As a policy matter, CMS has elected to impose a similar restriction on some participants in other ACO initiatives through the participation agreements for the various models.

included in the OCM episode. In addition, to account for the savings generated by the RO Model discount and withhold amounts, we would add the RO Model's discount and withhold amounts to the total cost of the OCM episode during OCM's reconciliation process to ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models.

In those cases where the RO Model episode would occur partially within an OCM episode and partially before or after the OCM episode, we propose to allocate the RO Model payments for RT services and the RO Model discount and withhold amounts to the OCM episode on a prorated basis, based on the number of days of overlap. In this case, the prorated portion of the payment under the RO Model, based on the number of days of overlap with the OCM episode, would be included in the OCM episode's expenditures as well as the prorated portion of the RO Model discount and withhold, again based on the number of days of overlap with the OCM episode. Including the prorated discount and withhold amounts would ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models.

In those cases where the RO Model episode occurs entirely within or partially before or after the OCM episode, for the purpose of calculating OCM episode costs, we would assume that all withholds are eventually paid to the RO Participant under the RO Model, and that there are no payments to recoup. We believe a process to allocate exact amounts paid to the participants with different reconciliation timelines between the two models would be operationally complex.

We intend to continue to review the potential overlap with OCM if the RO Model is finalized as proposed, including whether there are implications for OCM's prediction model for setting risk-adjusted target episode prices, which include receipt of RT services. Since prospective episode payments made under the RO Model would not be affected by OCM, OCM would account for RO Model overlap in its reconciliation calculations, and OCM participants would be notified and provided with further information through OCM's typical channels of communication.

d. Bundled Payments for Care Improvement (BPCI) Advanced

BPCI Advanced is testing a new iteration of bundled payments for 37 clinical episodes (33 inpatient and 4 outpatient).[64] BPCI Advanced is based on a total cost of care approach with certain MS–DRG exclusions. While there are no cancer episodes included in the design of BPCI Advanced, a beneficiary in a RO episode could be treated by a provider or supplier that is participating in BPCI Advanced for one of the 37 clinical episodes included in BPCI Advanced. Since prospective episode payments made under the RO Model would not be affected by BPCI Advanced, BPCI Advanced would determine whether to account for RO Model overlap in its reconciliation calculations, and CMS would provide further information to BPCI Advanced participants through an amendment to their participation agreement.

19. Decision Not To Include a Hardship Exemption

We do not believe that a hardship exemption for RO participants under the Model is necessary, since in the Model's pricing methodology gives significant weight to historical experience in determining the amounts for participant-specific professional episode payments and participant-specific technical episode payments. This is particularly evident in PY1, where the proposed efficiency factor in section III.C.6.e(2) is 0.90 for all RO participants. Accordingly, we are not proposing such an exemption in this proposed rule, and will not include such an exemption in the final rule in this rulemaking.

However, to the extent any stakeholders disagree with our assessment, we welcome public input on whether a possible hardship exemption for RO participants under the Model might be necessary or appropriate, and if so, how it might be designed and structured while still allowing CMS to test the Model. We intend to use any input we receive on this issue to consider whether a hardship exemption might be appropriate in subsequent rulemaking for a future PY.

IV. End-Stage Renal Disease (ESRD) Treatment Choices Model

A. Introduction

The proposed End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, referred to in this section IV of the proposed rule as ''the Model,'' would test whether adjusting the current Medicare fee-for-service (FFS) payments for dialysis services would incentivize ESRD facilities and clinicians managing adult Medicare FFS beneficiaries with ESRD, referred to herein as Managing Clinicians, to work with their patients to achieve increased rates of home dialysis utilization and kidney and kidney-pancreas transplantation and, as a result, improve or maintain the quality of care and reduce Medicare expenditures. Both of these modalities (home dialysis and transplantation) have support among health care providers and patients as preferable alternatives to in-center hemodialysis (HD), but the utilization rate of these services in the United States (U.S.) has been below such rates in other developed nations.[65] In the proposed ETC Model, CMS would adjust Medicare payments under the ESRD Prospective Payment System (PPS) to ESRD facilities and payments under the Medicare Physician Fee Schedule (PFS) to Managing Clinicians paid the ESRD Monthly Capitation Payment (MCP) selected for participation in the Model. The payment adjustments would include an upward adjustment on home dialysis and home dialysis-related claims with claim through dates during the initial three years of the ETC Model, that is, between January 1, 2020 and December 31, 2022. In addition, we would make an upward or downward performance adjustment on all dialysis claims and dialysis-related claims with claim through dates between July 1, 2021 and June 30, 2026, depending on the rates of home dialysis utilization and kidney and kidney-pancreas transplantation among the beneficiaries attributed to these participating ESRD facilities and Managing Clinicians. The ETC Model would test whether such payment adjustments can reduce total program expenditures and improve or maintain quality of care for Medicare beneficiaries with ESRD.

B. Background

1. Rationale for the Proposed ESRD Treatment Choices Model

Beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD beneficiaries require dialysis or kidney transplantation in order to survive, as their kidneys are no longer able to perform life-sustaining functions. In recent years, ESRD

[64] Major joint replacement of the lower extremity is a multi-setting Clinical Episode category. Total Knee Arthroplasty (TKA) procedures can trigger episodes in both inpatient and outpatient settings.

[65] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018. Volume 2: End-stage Renal Disease (ESRD) in the United States. Chapter 11: International Comparisons. Figures 11–15, 11–16.

beneficiaries have accounted for about 1 percent of the Medicare population and accounted for approximately 7 percent of total Medicare spending.[66] Beneficiaries with ESRD face the need for coordinating treatment for many disease complications and comorbidities, while experiencing high rates of hospital admissions and readmissions and a mortality rate greatly exceeding that of the general Medicare population. In addition, studies during the past decade have reported higher mortality rates for dialysis patients in the U.S. compared to other countries.[67] [68]

ESRD is a uniquely burdensome condition; with uncertain survival, patient experience represents a critical dimension for assessing treatment. The substantially higher expenditures and hospitalization rates for ESRD beneficiaries compared to the overall Medicare population, and higher mortality than in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. We anticipate that the proposed ETC Model would maintain or improve the quality of care for ESRD beneficiaries and reduce expenditures for the Medicare program by creating incentives for health care providers to assist beneficiaries, together with their families and caregivers, to choose the optimal renal replacement modality for the beneficiary.

The majority of ESRD patients receiving dialysis receive HD in an ESRD facility. At the end of 2016, 63.1 percent of all prevalent ESRD patients—meaning patients already diagnosed with ESRD—in the U.S. were receiving HD, 7.0 percent were being treated with peritoneal dialysis (PD), and 29.6 percent had a functioning kidney transplant.[69] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home hemodialysis (HHD).[70] PD is rarely conducted within a facility. In section IV.B.2 of this proposed rule, we describe how current Medicare payment rules and a lack of beneficiary education result in a bias toward in-center HD, which is often not preferred by patients or practitioners. In proposing the ETC Model, we aim to test whether new payment incentives would lead to greater rates of home dialysis (both PD and HHD) and kidney transplantation. We provide evidence from published literature to support the projection that higher utilization rates for these specific interventions would likely reduce Medicare expenditures, while preserving or enhancing the quality of care for beneficiaries and, at the same time, enhance beneficiary choice, independence, and quality of life.

a. Home Dialysis

There are two general types of dialysis: HD, in which an artificial filter outside of the body is used to clean the blood; and PD, in which the patient's peritoneum, covering the abdominal organs, is used as the dialysis membrane. HD is conducted at an ESRD facility, usually 3 times a week, or at a patient's home, often at a greater frequency. PD most commonly occurs at the patient's home. (Although PD can be furnished within an ESRD facility, it is very rare. In providing background information for the proposed ETC Model, we consider PD to be exclusively a home modality.) Whether a patient selects HD or PD may depend on a number of factors, such as patient education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference.[71] [72]

When Medicare began coverage for individuals on the basis of ESRD in 1973, more than 40 percent of dialysis patients in the U.S. were on HHD. More favorable reimbursement for outpatient dialysis and the introduction in the 1970s of continuous ambulatory peritoneal dialysis, which required less intensive training, contributed to a relative decline in HHD utilization.[73] Overall, the proportion of home dialysis patients in the U.S. declined from 1988 to 2012, with the number of home dialysis patients increasing at a slower rate relative to the total number of all dialysis patients. As cited in a U.S. Government Accountability Office (GAO) report, according to USRDS data, approximately 16 percent of the 104,000 dialysis patients in the U.S. received home dialysis in 1988; however, by 2012, the rates of HHD and PD utilization were 2 and 9 percent, respectively.[74]

Additionally, an annual analysis performed by the USRDS in 2018 compared the rates of dialysis modalities for prevalent dialysis patients in the U.S. to 63 selected countries or regions around the world. In 2016, the U.S. ranked 27th in the percentage of beneficiaries that were dialyzing at home (12 percent). For example, the U.S. rate of home dialysis is significantly below those of Hong Kong (74 percent), New Zealand (47 percent), Australia (28 percent), and Canada (25 percent).[75]

A 2011 report on home dialysis in the U.S. related the relatively low rate of home dialysis in this country to factors that included educational barriers, the monthly visit requirement for the MCP under the PFS, the need for home care partner support, as well as philosophies and business practices of dialysis providers, such as staffing allocations, lack of independence for home dialysis clinics, and business-oriented restrictions that lead to inefficient supply distribution. The report recommended consolidated, collaborative efforts to enhance patient education among nephrology practices, dialysis provider organizations, hospital systems and kidney-related organizations, as well as additional educational opportunities and training for nephrologists and dialysis staff. With regard to CMS's requirement starting in 2011 that the physician or non-physician practitioner furnish at least one in-person patient visit per month for home dialysis MCP services, the report noted that CMS allows discretion to Medicare contractors to allow payment without a visit so long as there is evidence for the provision of services throughout the month. Nevertheless, the report concluded that notwithstanding this allowance the stated policy might potentially be a disincentive for physicians to promote home dialysis.

[66] Kirchoff SM. Medicare Coverage of End-Stage Renal Disease (ESRD). Congressional Research Service. August 16, 2018. p. 1.

[67] Foley RN, Hakim RM. Why Is the Mortality of Dialysis Patients in the United States Much Higher than the Rest of the World? Journal of the American Society of Nephrology. 2009; 20(7):1432–1435. doi:*https://doi.org/10.1681/ASN.2009030282.*

[68] Robinson B, Zhang J, Morgenstern H, et al. Worldwide, mortality is a high risk soon after initiation of hemodialysis. Kidney International.2014;85(1):158–165. Doi:10.1038/ki.2013.252.

[69] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[70] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[71] Stack AG. Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study. Journal of the American Society of Nephrology. 2002; 13: 1279–1287. Doi 1046–6673/1305–1279.

[72] Miskulin DC, et al. Comorbidity and Other Factors Associated With Modality Selection in Incident Dialysis Patients: The CHOICE Study. American Journal of Kidney Diseases. 2002; 39(2): 324–336. Doi 10.1053/ajkd.2002.30552.

[73] Blagg CR. A Brief History of Home Hemodialysis. Annals in Renal Replacement Therapy. 1996; 3: 99–105.

[74] Unites States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO–16–125). October 2015.

[75] United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 11: International Comparisons. Figure F11.12.

The report further commented that the low rate of home dialysis in the U.S. may result in part from patients' inability to perform self-care, and suggested providing support for home care partners. With respect to dialysis providers' business practices and philosophies, the report notes that dialysis providers differ in many ways and have different experiences that deserve attention and consideration with regard to potentially posing a barrier to the provision of home dialysis.[76]

The high rate of incident dialysis patients beginning dialysis through in-center HD in the U.S. is driven by a variety of factors including ease of initiation, physician experience and training, misinformation around other modalities, inadequate education for CKD beneficiaries, built-up capacity at ESRD facilities, and a lack of infrastructure to support home dialysis.[77] (Provision of home dialysis requires a system of distribution of supplies to patients, as well as allocation of staff and space within facilities for education, training, clinic visits, and supervision). One study indicated that patients' perceived knowledge about various ESRD therapies was correlated with their understanding of the advantages and disadvantages of the available treatment options.[78] Researchers have reported that greater support, training, and education to nephrologists, other clinicians, and patients would increase the use of both HHD and PD. A prospective evaluation of dialysis modality eligibility among patients with chronic kidney disease (CKD) stages III to V enrolled in a North American cohort study showed that as many as 85 percent were medically eligible for PD.[79] However, in one study, only one-third of ESRD patients beginning maintenance dialysis were presented with PD as an option, and only 12 percent of patients were presented with HHD as an option.[80] As shown by a national pre-ESRD education initiative, pre-dialysis education results in a 2- to 3- fold increase in the rate of patients initiating home dialysis compared with the U.S. home dialysis rate.[81] Another study reported 42 percent of patients preferring PD when the option was presented to them.[82]

Recent studies show substantial support among nephrologists and patients for dialysis treatment at home.[83] [84] [85] [86] [87] We believe that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD beneficiaries.

Research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center. Key factors that may be related to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for dialysis providers for providing home dialysis.[88] [89] [90] [91] [92] (Most studies on the comparative cost and effectiveness of different dialysis modalities assess PD versus HD. We believe that since the extent of in-center PD is negligible, and only approximately 2 percent of HD occurs at home, these studies are suitable for drawing conclusions regarding home versus in-center dialysis.) However, research on cost differences between in-center dialysis and home dialysis is limited to comparing costs for patients who currently dialyze at home to those who do not. As previously discussed, there are currently barriers to dialyzing at home that may result in selection bias. Put another way, beneficiaries who currently dialyze at home may be different in some way from beneficiaries who dialyze in-center that is otherwise the cause of the observed difference in overall medical expenditures. Patients may differ in terms of age, gender, race, and clinical issues such as presence of diabetes and origin of ESRD.[93] Despite selection bias present in existing research, we expect that increasing rates of home dialysis will likely decrease Medicare expenditures for ESRD beneficiaries, and this is something we would assess as part of our evaluation of the ETC Model, if finalized.

In addition, current research on patients in the U.S. and Canada indicates similar, or better, patient survival outcomes for PD compared to HD.[94] [95] [96] (As previously noted, most

[76] Golper TA, Saxena AB, Piraino B, Teitelbaum, I, Burkart, J, Finkelstein FO, Abu-Alfa A. Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. American Journal of Kidney Diseases. 2011; 58(6): 879–885.doi:10.1053/j.ajkd.2011.06.028

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[78] Finkelstein FO, Story K, Firanek C, Barr P, et al. Perceived knowledge among patients cared for by nephrologists about chronic kidney disease and end-stage renal disease therapies. *Kidney International* 2008; 9: 1178–1184. *https://doi.org/10.1038/ki.2008.376.*

[79] Mendelssohn DC. Mujais SK, Soroka, SD, et al. A prospective evaluation of renal replacement therapy modality eligibility. Nephrology Dialysis Transplantation. 2009; 24(2): 555–561. doi: *https://doi.org/10/1093/ndt/gfn484.*

[80] Mehrotra R, Marsh D, Vonesh E, Peters V, Nissenson A. Patient education and access of ESRD patients to renal replacement therapies beyond in-center hemodialysis. Kidney International. 2005; 68(1):378–390.

[81] Lacson E, Wang W, DeVries C, Leste K, Hakim RM, Lazarus M, Pulliam J. Effects of a Nationwide Predialysis Educational Program on Modality Choice, Vascular Access, and Patient Outcomes. American Journal of Kidney Diseases. 2011; 58(2): 235–242.doi:10.1053/j.ajkd.2011.04.015.

[82] Maaroufi A, Fafin C, Mougel S, Favre G, Seitz-Polski P, Jeribi A, Vido S, Dewismi C, Albano L, Esnault V, Moranne O. Patient preferences regarding choice of end-stage renal disease treatment options. American Journal of Nephrology. 2013; 37(4): 359–369. doi: 1159/000348822.

[83] Rivara MB, Mehrotra R. The Changing Landscape of Home Dialysis in the United States. Current Opinion in Nephrology and Hypertension.2014; 23(6):586–591.doi:10.1097/MNH0000000000000066.

[84] Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar Outcomes With Hemodialysis and Peritoneal Dialysis in Patients With End-Stage Renal Disease. Archives of Internal Medicine. 2011; 171(2): 110–118. Doi:10.1001/archinternmed.2010.352.

[85] Ghaffari et al. 2013.

[86] Ledebo I, Ronco C. The best dialysis therapy? Results from an international survey among nephrology professionals. Nephrology Dialysis Transplantation.2008;6:403–408.doi:10.1093/ndtplus/sfn148.

[87] Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrology News & Issues. September 2010; 36–44.

[88] Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home haemodialysis modalities compared with facility haemodialysis: A systematic review of full economic evaluations. Nephrology. 2014; 19: 459–470 doi: 10.1111/nep.12269.

[89] Walker R, Howard K, Morton R. Home hemodialysis: A comprehensive review of patient-centered and economic considerations. ClinicoEconomics and Outcomes Research. 2017; 9: 149–161.

[90] Howard K, Salkeld G, White S, McDonald S, Chadban S, Craig J, Cass A. The cost effectiveness of increasing kidney transplantation and home-based dialysis. Nephrology. 2009; 14: 123–132 doi: 10.1111/j.1440–1797.2008.01073.x.

[91] Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verreli M, Oliver M. Impact of Modality Choice on Rates of Hospitalization in Patients Eligible for Both Peritoneal Dialysis and Hemodialysis. Peritoneal Dialysis International. 2014; 34(1): 41–48 doi: 10.3447/pdi.2012.00257.

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[93] United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Table 1.

[94] Wong B, Ravani P, Oliver MJ, Holroyd-Leduc J, Venturato L, Garg AX, Quinn RR. Comparison of Patient Survival Between Hemodialysis and Peritoneal Dialysis Among Patients Eligible for Both Modalities. American Journal of Kidney Diseases. 2018; 71(3) 344–351. doi:10.1053/j.ajkd.2017.08.028.

[95] Kumar VA, Sidell MA, Jones JP, Vonesh EF. Survival of propensity matched incident peritoneal

Continued

research on the comparative effectiveness of different dialysis modalities compares PD to HD, but we believe these studies are suitable for comparing home to in-center dialysis, given that in-center PD is negligible and only approximately 2 percent of HD is conducted at home.) The USRDS shows lower adjusted all-cause mortality rates for 2013 through 2016 for PD compared to HD.[97] Therefore, we believe increased rates of PD associated with increased rates of home dialysis prompted by the proposed Model would at least maintain, and may improve, quality of care provided to ESRD beneficiaries. While studies from several nations observe that the survival advantage for PD may be attenuated following the early years of dialysis treatment (1 to 3 years), and also that advanced age and certain comorbidities among patients are related to less favorable outcomes for PD, a component of the Model's evaluation would be to assess the applicability of these findings to the U.S. population and Medicare beneficiaries, specifically if there is sufficient statistical power to detect meaningful variation.[98] [99] [100] [101] [102] [103] [104] Patient benefits of HHD and PD also can include better quality of life and greater independence.[105] [106] [107] As described in greater detail throughout this section IV of this proposed rule, one of the aims of the proposed ETC Model is to test whether new payment incentives would lead to greater rates of home dialysis.

b. Kidney Transplants

A kidney transplant involves surgically transplanting one healthy kidney from a living or deceased donor. A kidney-pancreas transplant involves simultaneously transplanting both a kidney and a pancreas, for patients who have kidney failure related to type 1 diabetes mellitus. While the kidney in a kidney-pancreas transplant may come from a living or deceased donor, the pancreas can only come from a deceased donor. Candidates for kidney transplant undergo a rigorous evaluation by a transplant center prior to placement on a waitlist, and once placed on the waitlist, potential recipients must maintain active status on the waitlist. The United Network for Organ Sharing (UNOS) maintains the waitlist for and conducts matching of deceased donor organs. ESRD beneficiaries already on dialysis continue to receive regular dialysis treatments while waiting for an appropriate organ.

A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with maintenance dialysis.[108] Additionally, this review finds that beneficiaries who receive transplants experience a better quality of life than treatment with chronic dialysis.[109]

Per-beneficiary-per-year Medicare expenditures for beneficiaries receiving kidney or kidney-pancreas transplants are often substantially lower than for those on dialysis.[110] The average dialysis patient is admitted to the hospital nearly twice a year, often as a result of infection, and approximately 35.4 percent of dialysis patients who are discharged are re-hospitalized within 30 days of being discharged.[111] Among transplant recipients, there are a lower rates of hospitalizations, emergency department visits, and readmissions.[112] While comparisons between patients on dialysis and those with functioning transplants rely on observational data, due to the ethical concerns with conducting clinical trials, the data nonetheless suggest better outcomes for ESRD patients that receive transplants.

Notwithstanding these outcomes, only 29.6 percent of prevalent ESRD patients in the U.S. had a functioning kidney transplant and only 2.8 percent of incident ESRD patients—meaning patients new to ESRD—received a pre-emptive kidney transplant in 2016.[113] A pre-emptive transplant is a kidney transplant that occurs before the patient requires dialysis. These rates are substantially below those of other developed nations. The U.S. was ranked 39th of 61 reporting countries in kidney transplants per 1,000 dialysis patients in 2016, with 39 transplants per 1,000 dialysis patients in 2016.[114] While the relatively low rate of transplantation in the U.S. may partly reflect the high numbers of dialysis patients and differences in the relative prevalence and incidence of ESRD, there are other likely contributing causes, such as differences in health care systems, the infrastructure supporting transplantation, and cultural factors.[115]

The main barrier to kidney transplant is the supply of available organs. Medicare is undertaking regulatory efforts to increase organ supply, discussed in section IV.B.3.a of this proposed rule. Further, we believe there are a number of things ESRD facilities and Managing Clinicians can do to assist their beneficiaries in securing a transplant. Access to kidney transplantation can be improved by increasing referrals to the transplant waiting list, increasing rates of deceased and living kidney donation, expanding the pools of potential donors and recipients, and reducing the likelihood

and hemodialysis patients in a United States health care system. Kidney International. 2014; 86: 1016–1022. doi:10.1038/ki.2014.224.

[96] Mehrotra et al. 2011.

[97] United States Renal Data System. Annual Data Report, 2018. Volume 2, Chapter 5: Mortality. Figure 5.1. Mortality rates were adjusted for age, sex, race, ethnicity, primary diagnosis and vintage.

[98] Li KP, Chow KM. Peritoneal Dialysis—First Policy Made Successful: Perspectives and Actions. American Journal of Kidney Diseases. 2013; 62(5): 993–1005. doi: http://dx/doi.org/10.1053/j.ajkd.2013.03.038.

[99] Yeates K, Zhu N, Vonesh E, Trpeski L, Blake P, Fenton S. Hemodialysis and peritoneal dialysis are associated with similar outcomes for end-stage renal disease treatment in Canada. Nephrology Dialysis Transplantation. 2012; 27(9): 3568–3575. doi: *https://doi.org/10.1093/ndt/gfr/674.*

[100] Chiu YW, Jiwakanon S, Lukowsky L, Duong U, Kalantar-Zadeh, Mehrotra R. An Update on the Comparisons of Mortality Outcomes of Hemodialysis and Peritoneal Dialysis Patients. Seminars in Nephrology. 2011; 31(2): 152–158. Doi:10.1016/j.semnephrol.2011.01.004.

[101] Mehrotra et al. 2011.

[102] Sinnakirouchenan R, Holley JL. 2011.

[103] Quinn RR, Hux JE, Oliver MJ, Austin, PC, Tonelli M, Laupacis A. Selection Bias Explains Apparent Differential Mortality between Dialysis Modalities. Journal of the American Society of Nephrology. 2011; 22(8) 1534–1542. doi: 10.1681/ASN.2010121232.

[104] Weinhandl ED, Foley RN, Gilbertson DT, Arneson TJ, Snyder JJ, Collins AJ. Propensity-Matched Mortality Comparison of Incident Hemodialysis and Peritoneal Dialysis Patients. Journal of the American Society of Nephrology. 2010; 21(3): 499–506. doi: 10.1681/ASN.2009060635: 10.1681/ASN.2009060635.

[105] Ghaffari et al. 2013.

[106] Rivara and Mehrotra. 2014.

[107] Juergensen E, Wuerth D, Finkelstein SH et al., Hemodialysis and Peritoneal Dialysis: Patients' Assessments of Their Satisfaction with Therapy and the Impact of the Therapy on their Lies. Clinical Journal of American Society of Nephrology. 2006; 1(6): 1191–1196. DOI: *https://doi.org/10.2215/CJN.01220406.*

[108] Tonelli M, Weibe N, Knoll G, Bello A, Browne S. Jadhav D, Klarenbach S, Gill J. Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcomes. American Journal of Transplantation. 2011; 11(10). doi: *https://doi.org/10.1111/j.1600–6143.2011.03686.x.*

[109] Tonelli, M. et al. 2011.

[110] United States Renal Data System. Annual Data Report, 2018. Volume 2. Chapter 9: Healthcare expenditures for Persons with ESRD. Figure F9.8.

[111] United States Renal Data System. Annual Data Report, 2018; Volume 2, Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays. Tables F4–1, F4–8.

[112] United States Renal Data System. Annual Data Report, 2018: Volume 2, Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays. Tables F4.1, F4.8, and F4.14.

[113] United States Renal Data System. Annual Data Report, 2018; Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[114] United States Renal Data System. Annual Data Report, 2018. Volume 2. Chapter 11. International Comparisons. Figure 11.16.

[115] United States Renal Data System. Annual Data Report, 2018: Volume 2. Chapter 11. International Comparisons. *https://www.usrds.org/2018/view/v2_11.aspx.*

that potentially viable organs are discarded.[116] We anticipate that Managing Clinicians and ESRD facilities selected for participation in the proposed ETC Model would address these areas of improvement through various strategies in order to improve their rates of transplantation. These strategies could include educating beneficiaries about transplantation, coordinating care for beneficiaries as they progress through the transplant waitlist process, and assisting beneficiaries and potential donors with issues surrounding living donation, including support for paired donations and donor chains. In paired donations and donor chains, willing donors who are incompatible with their intended recipient can donate to other candidates on the transplant waitlist in return for a donation from another willing donor who is compatible with their intended recipient.[117]

After increasing during the 1990s, the volume of simultaneous pancreas and kidney transplants has either remained stable or declined slightly since the early 2000s. The reason for this decline is not clear, but is likely to be multifactorial, possibly including a decrease in patients being placed on the waiting list for this procedure, more stringent donor selection, and greater scrutiny of transplant center outcomes.[118]

Under current Medicare payment systems, an ESRD beneficiary receiving a kidney transplant represents a loss of revenue to the ESRD facility and, to a lesser extent, the Managing Clinician. After a successful transplant occurs, the ESRD facility no longer has a care relationship with the beneficiary, as the beneficiary no longer requires maintenance dialysis. While the Managing Clinician may continue to have a care relationship with the beneficiary post-transplant, payment for physicians' services related to maintaining the health of the transplanted kidney is lower than the MCP for managing dialysis. Whereas a Managing Clinician sees a beneficiary on dialysis and bills for the MCP each month, a post-transplant beneficiary requires fewer visits per year, and these visits are of a lower intensity. As described in greater detail throughout this section IV of this proposed rule, one of the aims of the proposed ETC Model is to test whether new payment incentives would lead to greater rates of kidney transplantation.

c. Addressing Care Deficits Through the ETC Model

Considering patient and clinician support for home dialysis and kidney transplant for ESRD patients, along with evidence that use of these treatment modalities could be increased with education, we propose to implement the ETC Model to test whether adjusting Medicare payments to ESRD facilities under the ESRD PPS and to Managing Clinicians under the PFS would increase rates of home dialysis, both HHD and PD, and kidney and kidney-pancreas transplantation.

We propose that the ETC Model would include two types of payment adjustments: The Home Dialysis Payment Adjustment (HDPA), and the Performance Payment Adjustment (PPA). The HDPA would be a positive payment adjustment on home dialysis and home dialysis-related claims during the initial three years of the Model, to provide an up-front incentive for ETC Participants to provide additional support to beneficiaries choosing to dialyze at home. The PPA would be a positive or negative payment adjustment, which would increase over time, on dialysis and dialysis-related claims, both home and in-center, based on the ETC Participant's home dialysis rates and transplant rates during a Measurement Year in comparison to achievement and improvement benchmarks, with the aim of increasing the percent of ESRD beneficiaries either having received a kidney transplant or receiving home dialysis over the course of the ETC Model. The magnitude of the HDPA would decrease as the magnitude of the PPA increases, to shift from a process-based incentive approach (the HDPA) to an outcomes-based incentive approach (the PPA).

The proposed payment adjustments under the ETC Model would apply to all Medicare-certified ESRD facilities and Managing Clinicians enrolled in Medicare located within selected geographic areas. While we propose to apply the HDPA to all ETC Participants, the PPA would not apply to certain ESRD facilities and Managing Clinicians managing low volumes of adult ESRD Medicare beneficiaries. One or both of the payment adjustments under the proposed ETC Model would apply to payments on claims for dialysis and certain dialysis-related services with through dates from January 1, 2020 through June 30, 2026, with the goal of reducing Medicare spending, preserving or enhancing quality of care for beneficiaries, and increasing beneficiary choice regarding ESRD treatment modality.

2. The Medicare ESRD Program

In this section, we describe current Medicare payment rules and how they may create both positive and negative incentives for the provision of home dialysis services and kidney transplants.

a. History of the Medicare ESRD Program

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) extended Medicare coverage to individuals regardless of age who have permanent kidney failure, or ESRD, requiring either dialysis or kidney transplantation to sustain life, and who meet certain other eligibility requirements. Individuals who become eligible for Medicare on the basis of ESRD are eligible for all Medicare-covered items and services, not just those related to ESRD. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292) amended Title XVIII of the Social Security Act (the Act) by adding section 1881.

Section 1881 of the Act establishes Medicare payment for services furnished to individuals who have been determined to have ESRD, including payments for self-care home dialysis support services furnished by a provider of services or renal dialysis facility, home dialysis supplies and equipment, and institutional dialysis services and supplies. Section 1881(c)(6) of the Act states: It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated. This provision also directs the Secretary of HHS to consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

Prior to 2011 and the implementation of the ESRD PPS, Medicare had a composite payment system for the costs incurred by ESRD facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether the services were furnished in a facility or at home. (For a discussion of the composite payment system,

[116] Serur D, Bingaman A, Smith B. Kidney Transplantation 2017 Breaking Down Barriers and Building Bridges. American Society of Nephrology: Kidney News Online. 2017; 9(4): *kidneynews.org/kidney-news/practice-pointers/kidney-transplantation-2017-breaking-down-barriers-and-building-bridges*.

[117] Segev D, Gentry S, Warren D. Kidney Paired Donation and Optimizing the Use of Live Donor Organs. JAMA. 2005;293(15):1883–1890. doi:10.1001/jama.293.15.1883.

[118] Redfield RR, Scalea JR, Odoricio JS. Simultaneous pancreas and kidney transplantation: Current trends and future directions. Current Opinion in Organ Transplantation. 2015; 20(1): 94–102. Doi:10.1097/MOT.0000000000000146.

please see 75 FR 49032). Under this methodology, prior to 2009, CMS differentiated between hospital-based and independent facilities for purposes of setting the payment rates. (Effective January 1, 2009, CMS discontinued the policy of separate payment rates based on this distinction 75 FR 49034). However, the same rate applied regardless of whether the dialysis was furnished in a facility or at a beneficiary's home. (75 FR 49058) The system was relatively comprehensive with respect to the renal dialysis services included as part of the composite payment, but over time a substantial portion of expenditures for renal dialysis services such as drugs and biologicals were not included under the composite payment and paid separately in accordance with the respective fee schedules or other payment methodologies (75 FR 49032). With the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), the Secretary was required to implement a payment system under which a single payment is made for renal dialysis services in lieu of any other payment.

In 2008, CMS issued a final rule entitled ''Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities,'' which was the first comprehensive revision since the outset of the Medicare ESRD program in the 1970s. The Conditions for Coverage (CfC) established by this final rule include separate, detailed provisions applicable to home dialysis services, setting substantive standards for treatment at home to ensure that the quality of care is equivalent to that for in-center patients. (73 FR 20369, 20409, April 15, 2008).

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA. The ESRD PPS is discussed in detail in the following section.

b. Current Medicare Coverage of and Payment for ESRD Services

The Medicare program covers a range of services and items associated with ESRD treatment. Medicare Part A generally includes coverage of inpatient dialysis for patients admitted to a hospital or skilled nursing facility for special care, as well as inpatient services for covered kidney transplants. Medicare Part B generally includes coverage of renal dialysis services furnished by Medicare-certified outpatient facilities, including certain dialysis treatment supplies and medications, home dialysis services, support and equipment, and doctor's services during a kidney transplant. Costs for medical care for a kidney donor are covered under either Part A or B, depending on the service. To date, Medicare Part C has been available to ESRD beneficiaries only in limited circumstances, such as when an individual already was enrolled in a Medicare Advantage (MA) plan at the time of ESRD diagnosis; however, as required under section 17006 of the 21st Century Cures Act, ESRD beneficiaries will be allowed to enroll in MA plans starting with 2021. Medicare Part D generally provides coverage for outpatient prescription drugs not covered under Part B, including certain renal dialysis drugs with only an oral form of administration (oral-only drugs), and prescription medications for related conditions.

(1) The ESRD PPS Under Medicare Part B

Under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all of the renal dialysis services and items defined in section 1881(b)(14)(B) of the Act and furnished to beneficiaries for the treatment of ESRD in a facility or in a patient's home. The ESRD PPS includes patient-level adjustments for case mix, facility-level adjustments for wage levels, low-volume facilities and rural facilities, and, when applicable, a training add-on for home and self-dialysis modalities, an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care, and a transitional drug add-on payment adjustment (TDAPA). Under section 1881(b)(14)(F) of the Act, the ESRD PPS payment amounts are increased annually by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

In implementing the ESRD PPS, we have sought to create incentives for providers and suppliers to offer home dialysis instead of just dialysis at a facility. In the CY 2011 ESRD PPS final rule, we noted that in determining payment under the ESRD PPS, we took into account all costs necessary to furnish home dialysis treatments including staff, supplies, and equipment. In that rule, we described that Medicare would continue to pay, on a per treatment basis, the same base rate for both in-facility and home dialysis, as well as for all dialysis treatment modalities furnished by an ESRD facility (HD and the various forms of PD) (75 FR 49057, 49059, 49064). The CY 2011 ESRD PPS final rule also finalized a wage-adjusted add-on per treatment adjustment for home and self-dialysis training under 42 CFR 413.235(c), as CMS recognized that the ESRD PPS base rate alone does not account for the staffing costs associated with one-on-one focused home dialysis training treatments furnished by a registered nurse (75 FR 49064). CMS noted, however, that because the costs associated with the onset of dialysis adjustment and the training add-on adjustment overlap, ESRD facilities would not receive the home dialysis training adjustment in addition to the add-on payment under the ESRD PPS for the first 4 months of dialysis for a Medicare patient (75 FR 49063, 49094).

ESRD PPS payment requirements are set forth in 42 CFR part 413, subpart H. Since the implementation of the ESRD PPS, CMS has published annual rules to make routine updates, policy changes, and clarifications. Payment to ESRD facilities under the ESRD PPS for a calendar year may also be reduced by up to two percent based on their performance under the ESRD QIP, which is authorized by section 1881(h) of the Act. Section 1881(h) of the Act requires the Secretary to select measures, establish performance standards that apply to the measures, and develop a methodology for assessing the total performance for each renal dialysis facility based on the performance standards established with respect to the measures for a performance period. CMS uses notice and comment rulemaking to make substantive updates to the ESRD PPS and ESRD QIP program requirements.

(2) The MCP

Medicare pays for routine professional services relating to dialysis care directly to a billing physician or non-physician practitioner. When Medicare pays the physician or practitioner separately for routine dialysis-related physicians' services furnished to a dialysis patient, the payment is made under the Medicare physician fee schedule using the MCP method as specified in 42 CFR 414.314. The per-beneficiary per-month MCP is for all routine physicians' services related to the patient's renal condition. Whereas the MCP for patients dialyzing in-center varies based on the number of in-person visits the physician has with the patient during the month, the MCP for patients dialyzing at home is the

same regardless of the number of in-person visits.[119]

(3) The Kidney Disease Education Benefit

In addition to establishing the ESRD PPS, the MIPPA, in section 152(b), amended section 1861(s)(2) of the Act by adding a new subparagraph (EE) ''kidney disease education services'' as a Medicare-covered benefit under Part B for beneficiaries with Stage 4 CKD. Medicare currently covers up to 6 1-hour sessions of KDE services, addressing the choice of treatment (such as in-center HD, home dialysis, or kidney transplant) and the management of comorbidities, among other topics (74 FR 61737, 61894).

However, utilization of KDE services has been low. Citing the USRDS, GAO reported that less than 2 percent of eligible Medicare beneficiaries used the KDE benefit in 2010 and 2011, the first 2 years it was available, and that use of the benefit has decreased since then.[120] According to GAO, stakeholders have attributed this low usage to the statutory restrictions on which practitioners can provide this service, and also the limitation of eligibility to the specific category of Stage 4 CKD patients. These restrictions are specified in section 1861(ggg)(1) and (2) of the Act. A ''qualified person'' is a physician, physician assistant, or nurse practitioner. Also, a provider of services located in a rural area is eligible as a ''qualified person'' to provide the service. GAO cited literature emphasizing the importance of pre-dialysis education in helping patients to make informed treatment decisions, and indicating that patients who have received such education might be more likely to choose home dialysis.

c. Impacts of Medicare Payment Rules on Home Dialysis

In the CY 2011 ESRD PPS final rule, we acknowledged concerns from commenters that the proposed ESRD PPS might contribute to decreasing rates of home dialysis. In particular, commenters stated that the single payment method would require ESRD facilities to bear the supply and equipment costs associated with home dialysis modalities, and thus make them less economically feasible. We noted in response that while home dialysis suppliers may not achieve the same economies of scale as ESRD facilities, suppliers would remain able to provide equipment and supplies to multiple ESRD facilities and be able to negotiate competitive prices with ESRD equipment and supply manufacturers (75 FR 49060). Nevertheless, we stated that we would monitor utilization of home dialysis under the ESRD PPS (75 FR 49057, 49060).

A May 2015 report from GAO examined the incentives for home dialysis associated with Medicare payments to ESRD facilities and physicians. Citing the USRDS, GAO found a decrease in the percentage of home dialysis patients as a percentage of all dialysis patients between 1988 and 2008, but then a slight increase to 11 percent in 2012.[121] According to GAO, the more recent increase in use of home dialysis was also reflected in CMS data for adult Medicare dialysis patients, showing an increase from 8 percent using home dialysis in January 2010 to about 10 percent as of March 2015.

Although this increase was generally concurrent with the phase-in of the ESRD PPS, the GAO report identified factors that might undermine incentives to encourage home dialysis. According to interviews with stakeholders, facilities' costs for increasing provision of in-center HD may be lower than for either HHD or PD. Although the average cost of an in-center HD treatment is typically higher than the average cost of a PD treatment, ESRD facilities may be able to add an in-center patient without incurring the cost of an additional dialysis machine because each machine can be used by 6 to 8 patients. In contrast, when adding a home dialysis patient, facilities generally incur costs for additional equipment specific to individual patients.[122]

Similarly, GAO received comments from physicians and physician organizations that Medicare payment may lead to a disincentive to prescribe home dialysis, because management of a home dialysis patient often occurs in a private setting and tends to be more comprehensive, while visits to multiple in-center patients may be possible in the same period of time. The GAO report noted, on the other hand, that monthly physician payments for certain patients under 65 who undergo home dialysis training may begin the first month, instead of the fourth, of dialysis, which may provide physicians with an incentive to prescribe home dialysis. In addition, the GAO report stated that Medicare makes a one-time payment for each patient who has completed home dialysis training under the physician's supervision.[123]

The GAO report concluded that interviews with stakeholders indicated potential for further growth, noting that the number and percentage of patients choosing home dialysis had increased in the recent years. The report stated that Medicare payments to facilities and physicians would need to be consistent with the goal of encouraging home dialysis when appropriate. A specific recommendation was to examine Medicare policies regarding monthly Medicare payments to physicians and revise them if necessary to encourage physicians to prescribe home dialysis for patients for whom it is appropriate.[124]

In the CY 2017 ESRD PPS final rule, CMS finalized an increase to the home and self-dialysis training add-on payment adjustment (81 FR 77856), to provide an increase in payment to ESRD facilities for training beneficiaries to dialyze at home.

3. CMS Efforts To Support Modality Choice

While CMS has taken steps in the past to support modality choice, the deficits in care previously described—low rates of home dialysis and kidney transplantation—remain. The proposed ETC Model is consistent with several different recent actions to support the goal of modality choice for ESRD beneficiaries, which are described in this proposed rule.

a. Regulatory Efforts

On September 20, 2018, CMS published in the **Federal Register** a proposed rule entitled ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction.'' (83 FR 47686). The proposed rule would, among other things, remove the requirements at 42 CFR 482.82 that currently require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. CMS proposed to remove these requirements in order to address unintended consequences of existing requirements, which have resulted in transplant programs potentially avoiding performing transplant procedures on certain patients and many organs with perceived risk factors going unused out of fear of being

[119] Medicare Claims Processing Manual, Chapter 8, 140; *https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf.*

[120] United States Government Accountability Office 2015.

[121] United States Government Accountability Office, 2015.

[122] United States Government Accountability Office, 2015.

[123] United States Government Accountability Office, 2015.

[124] United States Government Accountability Office. 2015.

penalized for outcomes that are non-compliant with § 482.82. According to the proposed rule, transplant programs have avoided using these kidneys for fear of non-compliance with the Conditions of Participation for transplant centers in hospitals (§§ 482.80 and 482.82) and potential Medicare termination of the program, despite evidence to the contrary that the use of these kidneys would not pose a problem for transplant recipients. Although CMS proposed to remove certain requirements at § 482.82, CMS emphasized that transplant programs should focus on maintaining high standards that protect patient health and safety and produce positive outcomes for transplant recipients. CMS stated that the agency will continue to monitor and assess outcomes, after initial Medicare approval. (83 FR 47706)

On November 14, 2018, CMS published in the **Federal Register** a final rule entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS'' (CY 2019 ESRD PPS final rule) (83 FR 56922). In that final rule, CMS adopted a new measure for the ESRD Quality Incentive Program (QIP) beginning with PY 2022, entitled the Percentage of Prevalent Patients Waitlisted (PPPW) measure, and placed that measure in the Care Coordination domain for purposes of performance scoring under the program. The adoption of this measure reflects CMS's belief that ESRD facilities should make better efforts to ensure that their patients are appropriately waitlisted for transplants (83 FR 57006). The proposed ETC Model would provide greater incentives for ESRD facilities and Managing Clinicians participating in the Model to assist ESRD beneficiaries with navigating the transplant process, including coordinating care to address clinical and non-clinical factors that impact eligibility for wait-listing and transplantation.

b. Alternative Payment Models

Recognizing the importance of ensuring quality coordinated care to beneficiaries with ESRD, in 2015, CMS began testing the Comprehensive ESRD Care (CEC) Model. The CEC Model is an accountable care model in which dialysis facilities, nephrologists, and other health care providers join together to form ESRD Seamless Care Organizations (ESCOs) that are responsible for the cost and quality of care for aligned beneficiaries. Although there are no specific incentives under the CEC Model relating to home dialysis, CMS evaluated whether total cost of care incentives caused an increase in the rate of home dialysis, as would be predicted by some of the literature, during the first year of the CEC Model. To date, the evaluation has not shown any statistically significant impact on the rates of home dialysis among CEC Model participants.[125] Although the evaluation results available for the CEC Model thus far are limited, based on these preliminary findings CMS believes that more targeted, system-wide incentives may be necessary to encourage modality choices and that the agency must provide explicit incentives in order to affect behavior changes by providers and suppliers.

On July 10, 2019, CMS announced four voluntary kidney models: The Kidney Care First (KCF) Model, and three Comprehensive Kidney Care Contracting (CKCC) Models. These models build on the existing CEC Model, and include incentives for coordinating care for aligned beneficiaries with CKD or ESRD and for reducing the total cost of care for these beneficiaries, as well as providing financial incentives for successful transplants. We view the KCF Model and the CKCC Models as complementary to the proposed ETC Model, as both models would incentivize a greater focus on kidney transplants. We propose that ESRD facilities and Managing Clinicians may participate in both the ETC Model and either the KCF Model or one of the CKCC Models, as discussed in section IV.C.6. of this proposed rule.

C. Provisions of the Proposed Regulation

1. Proposal To Implement the ETC Model

In this section IV of the proposed rule, we propose our policies for the ETC Model, including model-specific definitions and the general framework for implementation of the ETC Model. The proposed payment adjustments are designed to support increased utilization of home dialysis modalities and kidney and kidney-pancreas transplants that may, according to the literature described earlier in this section IV of the rule, be subject to barriers. Specifically, with regard to home dialysis, we acknowledge the possible need for ESRD facilities to invest in new systems that ensure that appropriate equipment and supplies are available in an economical manner to support greater utilization by beneficiaries. We also recognize that dialysis providers, nephrologists, and other clinicians would need to enhance education and training, both for patients and professionals, that there are barriers to patients choosing and accepting home dialysis modalities, and that the appropriateness of home dialysis as a treatment option varies among patients according to demographic and clinical characteristics, as well as personal choice.

As previously described, the duration of the payment adjustments under the ETC Model would be 6 years and 6 months, beginning on January 1, 2020, and ending on June 30, 2026. We also considered an alternate start date of April 1, 2020, to allow more time to prepare for Model implementation. If the ETC Model were to begin April 1, 2020, all intervals within the currently proposed timelines, including the periods of time for which claims would be subject to adjustment by the HDPA and the Measurement Years and Performance Payment Adjustment Periods used for purposes of applying the PPA, would remain the same length, but start and end dates would be adjusted to occur 3 months later. We seek comment on the alternative start date, April 1, 2020, and the subsequent three month adjustment to all ETC Model dates, including the implementation of the HDPA and PPA.

We are also including the following proposals for the Model: (a) The method for selecting ESRD facilities and Managing Clinicians for participation; (b) the schedule and methodologies for payment adjustments under the Model, and waivers of Medicare payment requirements necessary solely to test these methodologies under the Model; (c) the performance assessment methodology for ETC Participants, including the proposed methodologies for beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score; (d) monitoring and evaluation, including quality measure reporting; and (e) overlap with other CMS models and programs.

We propose to codify the definitions and policies of the ETC Model at subpart C of part 512 of 42 CFR (proposed §§ 512.300 through 512.397).

[125] Marrufo G, et al. Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 1 Annual Evaluation Report. CMS Innovation Center. November 2017; *innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf.*

We discuss the proposed definitions in section IV.C.2 of this proposed rule and each of the proposed regulatory provisions under the applicable subject area later. Section II of this proposed rule proposes that the general provisions proposed to be codified at §§ 512.100 through 512.180 would apply to both the proposed ETC Model and the proposed RO Model described in section III of this proposed rule.

2. Definitions

We propose at § 512.310 to define certain terms for the ETC Model. We describe these proposed definitions in context throughout this section IV of this proposed rule. We seek comment on the proposed definitions as a part of our seeking comment on the proposed policies for the ETC Model. If finalized, the definitions proposed in section II of this proposed rule also would apply to the ETC Model.

3. ETC Participants

a. Mandatory Participation

We propose to require all Managing Clinicians and all ESRD facilities located in selected geographic areas to participate in the ETC Model. We propose to define ''selected geographic area(s)'' as those Hospital Referral Regions (HRRs) selected by CMS, as described in section IV.C.3.b of this proposed rule, for purposes of selecting ESRD facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants. Our proposed definition of ''Hospital Referral Regions (HRRs)'' is described in section IV.C.3.b of the proposed rule.

For purposes of the ETC Model, we propose to define ''ESRD facility'' as defined in 42 CFR 413.171. Under § 413.171, an ESRD facility is an independent facility or a hospital-based provider of services (as described in 42 CFR 413.174(b) and (c)), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 and meets the supervision requirements described in 42 CFR part 494, and that furnishes institutional dialysis services and supplies under 42 CFR 410.50 and 410.52. We propose this definition because this is the definition used by Medicare for the ESRD PPS. We considered creating a definition specific to the ETC Model; however, we believe that the ESRD PPS definition of ESRD facility captures all facilities that furnish renal dialysis services that we are seeking to include as participants in the ETC Model.

For purposes of the ETC Model, we propose to define ''Managing Clinician'' as a Medicare-enrolled physician or non-physician practitioner who furnishes and bills the MCP for managing one or more adult ESRD beneficiaries. We considered limiting the definition to nephrologists, or other specialists who furnish dialysis care to beneficiaries with ESRD, for purposes of the ETC Model. However, analyses of claims data revealed that a variety of clinician specialty types manage ESRD beneficiaries and bill the MCP, including non-physician practitioners. We believe that the proposed approach to defining Managing Clinicians more accurately captures the set of practitioners we are seeking to include as participants in the ETC Model, rather than limiting the scope to self-identified nephrologists.

The ETC Model would require the participation of ESRD facilities and Managing Clinicians in selected geographic areas that might not otherwise participate in a payment model involving payment adjustments based on participants' rates of home dialysis and kidney transplants. Participation in other CMS models focused on ESRD, such as the CEC Model the KCF Model, and the CKCC Models, is optional. Interested individuals and entities must apply to such models during the applicable application period(s) to participate. To date, we have not tested an ESRD-focused payment model in which ESRD facilities and Managing Clinicians have been required to participate. We considered using a voluntary design for the ETC Model as well; however, we believe that a mandatory design has advantages over a voluntary design that are necessary to test this Model, in particular. First, we believe that testing a new payment model specific to encouraging home dialysis and kidney transplants may require the engagement of an even broader set of ESRD care providers than have participated in CMS models to date, including providers and suppliers who would participate only in a mandatory ESRD payment model. We are concerned that only a non-representative and relatively small sample of providers and suppliers, namely those that already have higher rates of home dialysis or kidney transplants relative to the national benchmarks, would participate in a voluntary model, which would not provide a robust test of the proposed payment incentives. In addition, because kidney and kidney-pancreas transplants are rare events—fewer than 4 percent of ESRD beneficiaries received such a transplant in 2016—we need a large number of beneficiaries to be included in the model test and comparison groups in order to detect a change in the rate of transplantation under the ETC Model.

Second, we believe that a mandatory design combined with randomized selection of a subset of geographic areas would enable CMS to better assess the effect of the Model's interventions on ETC Participants against a contemporaneous comparison group. As described in greater detail elsewhere in this section IV of the proposed rule, we propose to require participation by a subset of all ESRD facilities and Managing Clinicians in the U.S., selected based on whether they are located in a selected geographic area. Also, we propose to evaluate the impact of adjusting payments to Managing Clinicians and ESRD facilities by comparing the clinical and financial outcomes of ESRD facilities and Managing Clinicians located in these selected geographic areas against that of ESRD facilities and Managing Clinicians located in comparison geographic areas. Because both ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model would be representative of the larger dialysis market, many of the stakeholders in which operate on a nationwide basis, CMS would be able to generate more generalizable results. This proposed model design would therefore make it easier for CMS to evaluate the impact of the Model, as required under section 1115A(b)(4) of the Act, and to predict the impact of expanding the Model under section 1115A(c) of the Act, if authorized, while also limiting the scope of the model test to selected geographic areas.

We invite public comments on our proposal for mandatory participation, as well as our proposal to select ETC Participants based on their location in a selected geographic area.

b. Selected Geographic Areas

We propose to use an ESRD facility's or Managing Clinician's location in selected geographic areas, randomly selected by CMS, as the mechanism for selecting ETC Participants. We believe that geographic areas would provide the best means to establish the group of providers and suppliers selected for participation in the Model and the group of providers and suppliers not selected for participation in the Model to answer the primary evaluation questions described in section IV.C.11 of this proposed rule. Specifically, by using geographic areas as the unit for randomized selection, we would be able to study the impact of the Model on program costs and quality of care, both

overall and between ESRD facilities and Managing Clinicians selected for participation in the proposed Model and those ESRD facilities and Managing Clinicians not selected for participation in the Model.

To improve the statistical power of the Model's evaluation, we aim to include in the Model approximately 50 percent of adult ESRD beneficiaries. To achieve this goal, we propose to assign all geographic areas, specifically HRRs, into one of two categories: Selected geographic areas (those geographic areas for which ESRD facilities and Managing Clinicians located in the area would be selected for participation in the ETC Model and would be subject to the Model's Medicare payment adjustments for ESRD care, if finalized); and comparison geographic areas (those geographic areas for which ESRD facilities and Managing Clinicians located in the area would not be selected for participation in the ETC Model and thus would be subject to customary Medicare payment for ESRD care). Given the national scope of the major stakeholders in the dialysis market and the magnitude of the payment adjustments proposed for this Model, we believe a broad geographic distribution of participants would be necessary to effectively test the impact of the proposed payment adjustments.

We propose to use HRRs as the geographic unit of selection for selecting ETC Participants. An HRR is a unit of analysis created by the Dartmouth Atlas Project to distinguish the referral patterns to tertiary care for Medicare beneficiaries, and is composed of groups of zip codes. The Dartmouth Atlas Project data source is publicly available at *https://www.dartmouthatlas.org/.* Therefore, we propose to define the term ''HRRs'' to mean the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at *https://www.dartmouthatlas.org/.*

With 306 HRRs in the U.S., we believe there would be a sufficient number of HRRs to support random selection and improve statistical power of the proposed Model's evaluation. We conducted power calculations for the outcomes of home dialysis and kidney and kidney pancreas transplant utilization. For home dialysis, the CMS Office of the Actuary (OACT) forecasts an average increase of 1.5 percentage points per year. With a current home dialysis rate of 8.6 percent,[126] this represents an increase of 18 percent. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need few HRRs included in the intervention group However for transplants, which are rare events, a substantial number of HRRs would be needed to detect changes. OACT did not assume any change in its main projections but estimated that an additional 2,360 transplants would occur over the course of the proposed Model due to a lower discard rate for deceased donor organs. With 20,161 transplants currently conducted on an annual basis,[127] this represents an 11.7 percent increase over 5 years. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need approximately 153 HRRs in the intervention group, which represents 50 percent of the 306 HRRs in the US. We believe random selection with a large sample of units, such as the 306 HRRs, would safeguard against uneven distributions of factors among selected geographic areas and comparison geographic areas, such as urban or rural markets, dominance of for-profit dialysis organizations, and dense population areas with greater access to transplant centers.

We considered using Core Based Statistical Areas (CBSAs) or Metropolitan Statistical Areas (MSAs) as the geographic unit of selection. However, neither CBSAs nor MSAs include rural areas and, due to the nature of dialysis treatment, we believe inclusion of rural providers and suppliers is vital to testing the Model. Specifically, as a significant proportion of beneficiaries receiving dialysis live in rural areas and receive dialysis treatment from providers and suppliers located in rural areas, we believe using a geographic unit of selection that does not include rural areas would limit the generalizability of the model findings to this population.

We also considered using counties or states as the geographic unit of selection. However, we determined that counties would be too small and therefore too operationally challenging to use for this purpose, both due to the high number of counties and the relatively small size of counties such that a substantial number of Managing Clinicians practice in multiple counties. We also determined that states would be too heterogeneous in population size, and that using states could confound the model test due to potential variation in state-level regulations relating to ESRD care. Additionally, the use of counties or states could introduce confounding spillover effects, such as where ESRD beneficiaries receive care from a Managing Clinician in a county or state selected for the Model and dialyze in a county or state not selected for the Model, thus mitigating the effect of the Model's incentives on the beneficiary's overall care. HRRs are derived from Medicare data based on hospital referral patterns, which are correlated with dialysis and transplant referral patterns and which would therefore mitigate potential spillover effects of this nature. In the alternative, we would consider using CBSAs as the geographic unit of selection, and assigning rural counties not included in CBSAs to the nearest CBSA, as this approach would use an existing methodology already used by CMS to denote regions (CBSAs, which are used, among other things, in determining the wage index adjustments to Medicare inpatient prospective payment system rates to account for variation in hospital wages and wage-related costs related to location), while also making sure that a random selection of providers and suppliers located in rural areas are included as participants in the ETC Model.

We propose to establish the selected geographic areas by selecting a random sample of 50 percent of HRRs in all 50 states and the District of Columbia, stratified by region. Regional stratification would use the four Census-defined geographic regions: Northeast, South, Midwest, and West. Information about Census-defined geographic regions is available at *https://www.census.gov/geo/reference/gtc/gtc_census_divreg.html.* The stratification would control for regional patterns in practice variation. If an HRR spans two or more Census-defined geographic regions, the HRR would be assigned to the region in which the HRR's associated state is located. For example, the Rapid City HRR centered in Rapid City, South Dakota, contains zip codes located in South Dakota and Nebraska, which are in the Midwest Census Region, and zip codes located in Montana and Wyoming, which are in the West Census Region. For the purposes of the regional stratification, we would consider the Rapid City HRR and all zip codes therein to be in the Midwest region, as its affiliated state, South Dakota, is in the Midwest region.

We propose that the U.S. Territories, as that term is proposed to be defined in section II of this proposed rule, would be excluded from selection, as HRRs are not constructed to include these areas.

[126] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[127] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 6: Transplantation. *https://www.usrds.org/2018/view/v2_06.aspx.*

In addition, outside of the randomization, we propose that all HRRs for which at least 20 percent of the component zip codes are located in Maryland would be selected for participation in the ETC Model, in conjunction with the Maryland Total Cost of Care (TCOC) Model currently being tested in Maryland. These HRRs would not be included in the randomization process previously described. CMS believes that the automatic inclusion of ESRD facilities and Managing Clinicians in these HRRs as participants in the ETC Model would be necessary because, while the Maryland TCOC Model includes incentives to lower the Medicare TCOC in the state, including state accountability for meeting certain Medicare TCOC targets, as well as global budget payments that hold Maryland hospitals accountable for the Medicare TCOC, there currently is no direct mechanism to lower the cost of care for ESRD beneficiaries specifically under the Maryland TCOC Model. We believe that adding Maryland-based ESRD facilities and Managing Clinicians as participants in the proposed ETC Model would assist the state of Maryland and hospitals located in that state to meet the Medicare TCOC targets established under the Maryland TCOC Model.

We propose that all HRRs that are not selected geographic areas would be referred to as ''comparison geographic area(s).'' We propose that comparison geographic areas would be used for the purposes of constructing performance benchmarks (as discussed in section IV.C.5.d of this proposed rule), and for the Model evaluation (as discussed in section IV.C.11 of this proposed rule).

We invite public comments on our proposal to use HRRs as the geographic unit of selection, with regional stratification, and to exclude U.S. Territories from the selected geographic areas. We invite comment on our alternative consideration to use CBSAs as the geographic unit of selection, and assign rural counties not included in CBSAs to the nearest CBSA. We also invite comment on the inclusion of all HRRs for which at least 20 percent of the component zip codes are located in Maryland, separate from the randomization, as well as whether HRRs that include areas included in the Pennsylvania Rural Health Model, the Vermont All-Payer ACO Model, or future state-based models tested under section 1115A of the Act should also be selected geographic areas for purposes of the ETC Model.

c. Participant Selection for the ETC Model

We propose to define ''ETC Participant'' as an ESRD facility or Managing Clinician that is required to participate in the ETC Model in accordance with proposed § 512.325(a), which describes the selection of model participants based on their location within a selected geographic area, as previously described. In addition, we note that the proposed definition of ''model participant,'' as defined in section II of this proposed rule, would include an ETC Participant.

(1) ESRD Facilities

We propose that all Medicare-certified ESRD facilities located in a selected geographic area would be required to participate in the ETC Model. We propose to determine ESRD facility location based on the zip code of the practice location address listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). We considered using the zip code of the mailing address listed in PECOS. However, we concluded that mailing address is a less reliable indicator of where a facility is physically located than the practice location address, as facilities may receive mail at a different location than where they are physically located.

We invite public comment on this proposal for identifying where ESRD facilities are located for purposes of selecting ESRD facilities for participation in the ETC Model.

(2) Managing Clinicians

We propose that all Medicare-enrolled Managing Clinicians located in a selected geographic area would be required to participate in the ETC Model. We propose to identify the Managing Clinician's location based on the zip code of the practice location address listed in PECOS. If a Managing Clinician has multiple practice location addresses listed in PECOS, we would use the practice location through which the Managing Clinician bills the plurality of his or her MCP claims. We considered using the zip code of the mailing address listed in PECOS. However, we determined that mailing address is a less reliable indicator of where a clinician physically practices than the practice location address, as clinicians may receive mail at a different location from where they physically practice.

We invite public comment on this proposal for identifying where Managing Clinicians are located for purposes of selecting Managing Clinicians for participation in the ETC Model.

4. Home Dialysis Payment Adjustment

We propose to positively adjust payments for home dialysis and home dialysis-related services billed by ETC Participants for claims with claim through dates during the first three CYs of the ETC Model (CY 2020–CY 2022). The HDPA would provide an up-front positive incentive for ETC Participants to support ESRD beneficiaries in choosing home dialysis. The HDPA would complement the PPA, described in section IV.C.5 of this proposed rule, which would begin in mid-CY 2021 and increase in magnitude over the duration of the Model; as such we propose that the HDPA would decrease over time as the magnitude of the PPA increases. There would be two types of HDPAs: The Clinician HDPA and the Facility HDPA. We propose to define the ''Clinician HDPA'' as the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant for the Managing Clinician's home dialysis claims, as described in proposed § 512.345 (Payments Subject to the Clinician HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We propose to define the ''Facility HDPA'' as the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in proposed § 512.340 (Payments Subject to the Facility HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We propose to define the ''HDPA'' as either the Facility HDPA or the Clinician HDPA. We do not believe that an analogous payment adjustment is necessary for increasing kidney transplant rates during the initial years of the ETC Model. Rather, instead of creating a payment adjustment, we propose to implement a learning collaborative that focuses on disseminating best practices to increase the supply of deceased donor kidneys available for transplant. For a description of the learning collaborative, see section IV.C.12 of this proposed rule.

a. Payments Subject to the HDPA

We propose that the HDPA would apply to all ETC Participants for those payments described in sections IV.C.4.b and IV.C.4.c of this proposed rule, according to the proposed schedule described in section IV.C.4.d of this proposed rule. We solicit comment on the proposal to apply the HDPA with

respect to all ETC Participants, without exceptions.

We also propose that the HDPA would apply to claims where Medicare is the secondary payer for coverage under section 1862(b)(1)(C) of the Act. When a beneficiary eligible for coverage under an employee group health plan becomes eligible for Medicare because he or she has developed ESRD, there is a 30 month coordination period during which the beneficiary's group health plan remains the primary payer if the beneficiary was previously insured. During this time, Medicare is the secondary payer for these beneficiaries. We propose to apply the HDPA to Medicare as secondary payer claims because the initial transition period onto dialysis is important for supporting beneficiaries in selecting home dialysis, as beneficiaries who begin dialysis at home are more likely to remain on a home modality. The HDPA would adjust the Medicare payment rate for the initial claim, and then the standard Medicare Secondary Payer calculation and payment rules would apply, possibly leading to an adjustment to the Medicare Secondary Payer amount. We seek comment on the proposal to apply the HDPA to Medicare as secondary payer claims.

b. Facility HDPA

For ESRD facilities that are ETC Participants, we propose to adjust Medicare payments under the ESRD PPS for home dialysis services by the HDPA according to the proposed schedule described in section IV.C.4.d of this proposed rule. As noted previously, under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all renal dialysis services and home dialysis services furnished to beneficiaries. This payment is subject to a number of adjustments, including patient-level adjustments, facility-level adjustments, and, when applicable, a training adjustment add-on for home and self-dialysis modalities, an outlier payment, and the TDAPA. The current formula for determining the final ESRD PPS per treatment payment amount is as follows:

Final ESRD PPS Per Treatment Payment Amount = (*Adjusted ESRD PPS Base Rate* + *Training Add On* + *TDAPA*) * *ESRD QIP Factor* + *Outlier Payment* * *ESRD QIP Factor*

Under our proposal, we would apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claims submitted for home dialysis services. For purposes of the ETC Model, we propose to define the ''Adjusted ESRD PPS per Treatment Base Rate'' as the per treatment payment amount as defined in 42 CFR 413.230, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount. The proposed formula for determining the final ESRD PPS per treatment payment amount with the Facility HDPA would be as follows:

$$\textit{Final Per Treatment Payment Amount with Facility HDPA} = \big((\textit{Adjusted ESRD PPS per Treatment Base Rate} * \textit{Facility HDPA}) + \textit{Training Add On} + \textit{TDAPA}\big) * \textit{ESRD QIP Factor} + \textit{Outlier Payment} * \textit{ESRD QIP Factor}$$

We considered adjusting the full ESRD PPS per treatment payment amount by the Facility HDPA, including any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA. However, we concluded that adjusting these additional payment amounts was not necessary to create the financial incentives we seek to test under the proposed ETC Model. We seek comment on our proposed definition of the Adjusted ESRD PPS per Treatment Base Rate, and the implications of excluding from the definition the adjustments and payment amounts previously listed, such that those amounts would not be adjusted by the Facility HDPA under the ETC Model.

We propose in § 512.340 to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claim lines with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with condition codes 74, 75, 76, or 80, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim through date during a CY subject to adjustment, as described in section IV.C.4.d of this proposed rule, where the beneficiary is age 18 or older during the entire month of the claim. Facility code 7 (the second digit of Type of Bill) paired with type of care code 2 (the third digit of Type of Bill), indicates that the claim occurred at a clinic or hospital-based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. Condition codes 74 and 75 indicate billing for a patient who received dialysis services at home, and condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. Condition code 76 indicates billing for a patient who dialyzed at home but received back-up dialysis in a facility. Taken together, we believe these condition codes capture home dialysis services furnished by ESRD facilities, and therefore are the codes we propose to use to identify those payments subject to the Facility HDPA. We seek comment on this proposed provision.

As further described in section IV.C.7.a of this proposed rule, we also propose that the Facility HDPA would not affect beneficiary cost sharing. Beneficiary cost sharing instead would be based on the amount that would have been paid under the ESRD PPS absent the Facility HDPA.

c. Clinician HDPA

For Managing Clinicians that are ETC Participants, we propose to adjust the MCP by the Clinician HDPA when billed for home dialysis services. We propose to define the ''MCP'' as the monthly capitated payment made for each ESRD beneficiary to cover all routine professional services related to treatment of the patient's renal condition furnished by a physician or non-physician practitioner as specified in 42 CFR 414.314. We considered adjusting all Managing Clinician claims for services furnished to ESRD beneficiaries, including those not for dialysis management services. However,

we concluded that adjusting claims for services other than dialysis management was not necessary to create the financial incentives we seek to test under the proposed ETC Model.

We propose in § 512.345 to adjust the amount otherwise paid under Part B with respect to MCP claims on claim lines with CPT® codes 90965 and 90966 by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant with a claim through date during a CY subject to adjustment, as described in section IV.C.4.d of this proposed rule, where the beneficiary is age 18 or older for the entire month of the claim. CPT® code 90965 is for ESRD related services for home dialysis per full month for patients 12–19 years of age. CPT® code 90966 is for ESRD related services for home dialysis per full month for patients 20 years of age and older. These two codes are used to bill the MCP for patients age 18 and older who dialyze at home, and therefore are the codes we propose to use to identify those payments subject to the HDPA. As noted previously, we propose to adjust the amount otherwise paid under Part B by the Clinician HDPA so that beneficiary cost sharing would not be affected by the application of the Clinician HDPA. The Clinician HDPA would apply only to the amount otherwise paid for the MCP absent the Clinician HDPA. We seek comment on this proposed provision.

d. HDPA Schedule and Magnitude

We propose in new § 512.350 that the magnitude of the HDPA would decrease over the CYs of the ETC Model test, as the magnitude of the PPA increases. In this way, we would transition from providing additional financial incentives to support the provision of home dialysis through the HDPA in the initial three CYs of the ETC Model, to holding ETC Participants accountable for attaining the outcomes that the Model is designed to achieve via the PPA. We considered alternative durations of the HDPA, including limiting the HDPA to one year such that there would be no overlap between the HPDA and the PPA, or extending the HDPA for the entire duration of the Model. However, we did not elect to propose these approaches. If the HDPA applied for only the first year of the Model, there would be a six month gap between the end of the HDPA (December 31, 2020) and the start of the first PPA period (July 1, 2021), during which there would be no model-related payment adjustment. If the HDPA applied for the duration of the Model, there would be two sets of incentives in effect: A process-based incentive from the HDPA and an outcomes-based incentive from the home dialysis component of the PPA. While we believe that the time-limited overlap between the two payment adjustments is acceptable to smoothly transition ETC Participants from process-based incentives to outcomes-based incentives, we do not believe this structure is beneficial to the Model test over the long term.

We propose the payment adjustment schedule in Table 11:

TABLE 11—PROPOSED HDPA SCHEDULE

	CY 2020	CY 2021	CY 2022
Magnitude of Payment Adjustment	+3%	+2%	+1%

Under this proposed schedule, the HDPA would no longer apply to claims submitted by ETC Participants with claim through dates on or after January 1, 2023. We seek input from the public about the proposed magnitude and duration of the proposed HDPA.

5. Performance Payment Adjustment

We propose to adjust payment for claims for dialysis services and dialysis-related services submitted by ETC Participants based on each ETC Participant's Modality Performance Score (MPS), calculated as described in section IV.C.5.d of this proposed rule. We propose to define the ''Modality Performance Score (MPS)'' as the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in proposed § 512.370(d) (Modality Performance Score), which is used to determine the amount of the ETC Participant's PPA, as described in proposed § 512.380 (PPA Amounts and Schedule). We seek comment on the composition of the MPS, particularly the inclusion of the transplant rate in the MPS.

There would be two types of PPAs: The Clinician PPA and the Facility PPA. We propose to define the ''Clinician PPA'' as the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in proposed § 512.375(b) (Payments Subject to Adjustment) and proposed § 512.380 (PPA Amounts and Schedule). We propose to define the ''Facility PPA'' as the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in proposed § 512.375(a) (Payments Subject to Adjustment) and proposed § 512.380 (PPA Amounts and Schedule). We propose to define the ''PPA'' as either the Facility PPA or the Clinician PPA.

a. Annual Schedule of Performance Assessment and PPA

We propose to assess ETC Participant performance on the home dialysis rate and the transplant rate, described in sections IV.C.5.c.1 and IV.C.5.c.2 respectively, of this proposed rule, and to make corresponding payment adjustments according to the proposed schedule described later. We propose in § 512.355(a) that we would assess the home dialysis rate and transplant rate for each ETC Participant during each of the Measurement Years, which would include 12 months of performance data. For the ETC Model, we propose to define ''Measurement Year (MY)'' as the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Further, we propose in § 512.355(b) that we would adjust payments for ETC Participants by the PPA during each of the PPA periods, each of which would correspond to a Measurement Year. We propose to define ''Performance Payment Adjustment Period (PPA Period)'' as the 6-month period during which a PPA is applied in accordance with proposed § 512.380 (PPA Amounts and Schedule). Each MY included in the ETC Model and its corresponding PPA Period would be specified in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods).

Under our proposal, each MY would overlap with the subsequent MY, if any, for a period of 6 months, as ETC Participant performance would be assessed and payment adjustments would be updated by CMS on a rolling basis. We believe that this method of making rolling performance assessments balances two important factors: The need for sufficient data to produce reliable estimates of performance, and the effectiveness of incentives that are proximate to the period for which performance is assessed. Beginning with MY 2, there would be a 6-month period of overlap between a MY and the previous MY. For example, MY 1 would begin January 1, 2020, and would run through December 31, 2020; and MY 2 would begin 6 months later, running from July 1, 2020, through June 30, 2021. Each MY would have a corresponding PPA Period, which would begin 6 months after the

conclusion of the MY. For example, MY 1, which would end December 31, 2020, would correspond to PPA Period 1, which would begin July 1, 2021, and end December 31, 2021.

In Table 12, we propose the following schedule of MYs and PPA Periods:

TABLE 12: ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

	Measurement Year (MY)		Performance Payment Adjustment (PPA) Period	
Beginning CY 2020	MY 1	1/1/2020 through 12/31/2020	PPA Period 1	7/1/2021 through 12/31/2021
	MY 2	7/1/2020 through 6/30/2021	PPA Period 2	1/1/2022 through 6/30/2022
Beginning CY 2021	MY 3	1/1/2021 through 12/31/2021	PPA Period 3	7/1/2022 through 12/31/2022
	MY 4	7/1/2021 through 6/30/2022	PPA Period 4	1/1/2023 through 6/30/2023
Beginning CY 2022	MY 5	1/1/2022 through 12/31/2022	PPA Period 5	7/1/2023 through 12/31/2023
	MY 6	7/1/2022 through 6/30/2023	PPA Period 6	1/1/2024 through 6/30/2024
Beginning CY 2023	MY 7	1/1/2023 through 12/31/2023	PPA Period 7	7/1/2024 through 12/31/2024
	MY 8	7/1/2023 through 6/30/2024	PPA Period 8	1/1/2025 through 6/30/2025
Beginning CY 2024	MY 9	1/1/2024 through 12/31/2024	PPA Period 9	7/1/2025 through 12/31/2025
	MY 10	7/1/2024 through 6/30/2025	PPA Period 10	1/1/2026 through 6/30/2026

We invite public comment on the proposed schedule of MYs and corresponding PPA Periods.

b. Beneficiary Population and Attribution

We propose that, in order to assess the home dialysis rate and transplant rate for ETC Participants, ESRD beneficiaries would be attributed to participating ESRD facilities and to participating Managing Clinicians. For purposes of the ETC Model, we propose to define ''ESRD Beneficiary'' as a beneficiary receiving dialysis or other services for end-stage renal disease, up to and including the month in which he or she receives a kidney or kidney-pancreas transplant. This would include beneficiaries who are on dialysis for treatment of ESRD, as well as beneficiaries who were on dialysis for treatment of ESRD and received a kidney or kidney-pancreas transplant up to and including the month in which they received their transplant.

Also, we propose to attribute pre-emptive transplant beneficiaries to Managing Clinicians for purposes of calculating the transplant rate, specifically. We propose to define a ''pre-emptive transplant beneficiary'' as a Medicare beneficiary who received a kidney or kidney-pancreas transplant prior to beginning dialysis. This definition would be mutually exclusive of the proposed definition of an ESRD Beneficiary, as a pre-emptive transplant beneficiary receives a kidney or kidney-pancreas transplant prior to initiating dialysis and therefore is not an ESRD Beneficiary. We considered defining this concept as pre-emptive transplant recipients, as there are patients who receive pre-emptive transplants who are not Medicare beneficiaries, but who would have become eligible for Medicare if they did not receive a pre-emptive transplant and progressed to ESRD, requiring dialysis. This definition would more accurately reflect the total number of transplants occurring in the population of patients who could receive pre-emptive transplants, and including these additional patients who receive pre-emptive transplants in the calculation of the transplant rate could better incentivize Managing Clinicians to support kidney transplants via the Clinician PPA. Due to data limitations about patients who are not Medicare beneficiaries, however, we concluded that we could not include patients who received pre-emptive transplants but were not Medicare beneficiaries in the construction of the transplant rate. Therefore, we are proposing to limit the definition of pre-emptive transplant beneficiary to include Medicare beneficiaries only.

We propose to attribute ESRD Beneficiaries, and pre-emptive transplant beneficiaries where applicable, to ETC Participants for each month of each MY, and we further propose that such attribution would be made after the end of each MY. We considered attributing beneficiaries to participating ESRD facilities and Managing Clinicians for the entire MY; however, we believe monthly attribution would more accurately capture the care relationship between beneficiaries and their ESRD providers and suppliers. As ETC Participant behavior and care relationships with beneficiaries may change as a result of the ETC Model, we believe that the level of precision associated with monthly attribution of beneficiaries would better support the ETC Model's design. Under our proposal, an ESRD Beneficiary may be attributed to multiple ESRD facilities and Managing Clinicians in one MY, but would be attributed to only one ESRD facility and one Managing Clinician for a given month during the MY. A pre-emptive transplant beneficiary may be attributed to only one Managing Clinician during a MY, regardless of the number of months for which the beneficiary is attributed to the Managing Clinician.

We considered conducting attribution prospectively, before the beginning of the MY. However, we concluded that prospective attribution would not be appropriate given the nature of ESRD and the ESRD beneficiary population. CKD is a progressive illness, with patients moving from late stage CKD to ESRD—requiring dialysis or a transplant—throughout the course of the year. In this case, we believe prospective attribution would functionally exclude incident beneficiaries new to dialysis from inclusion in the home dialysis and transplant rates of ETC Participants until the following MY. Additionally, we believe that prospective attribution would not work well for the particular design of this Model. In particular, because the PPA would be determined based on home dialysis and transplant rates during the MY, limiting attribution to beneficiaries with whom the ETC Participant had a care relationship prior to the MY would not accurately capture what occurred during the MY. We believe that conducting attribution retrospectively, after the completion of the MY, would better align with the design of the PPA in the ETC Model. We invite public comment on the proposal to attribute beneficiaries on a monthly basis after the end of the relevant MY.

We propose to provide ETC Participants lists of their attributed beneficiaries after attribution has occurred, after the end of the MY. We considered providing lists in advance of the MY, or on a more frequent basis. However, we determined that, since we would be conducting attribution after the conclusion of the MY, prospective lists of attributed beneficiaries that attempted to simulate which beneficiaries would be attributed to a participant during the MY would be potentially misleading. Additionally, as the calculation of the home dialysis rate and transplant rate among attributed beneficiaries would be conducted only once every 6 months due to overlapping MYs, we believe providing lists after the MY would provide ETC Participants sufficient information about their attributed beneficiary populations to understand the basis of their rates of home dialysis and transplants.

(1) Beneficiary Exclusions

We propose to exclude certain categories of beneficiaries from attribution to ETC Participants, consistent with other CMS models and programs. Specifically, we are proposing to exclude an ESRD Beneficiary or a pre-emptive transplant beneficiary if, at any point during the month, the beneficiary:

- Is not enrolled in Medicare Part B, because Medicare Part B pays for the majority of ESRD-related items and services, for which Part B claims are necessary for evaluation of the Model.
- Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plans, because these plans have different payment structures than Medicare Parts A and B and do not use FFS billing.
- Does not reside in the United States, because it is more difficult to track and assess the care furnished to beneficiaries who might have received care outside of the U.S.
- Is younger than age 18 at any point in the month, because beneficiaries under age 18 are more likely to have ESRD from rare medical conditions that have different needs and costs associated with them than the typical ESRD beneficiary.
- Has elected hospice, because hospice care generally indicates cessation of dialysis treatment and curative care.
- Is receiving dialysis for acute kidney injury (AKI) only, because renal dialysis services for AKI differ in care and costs from a typical ESRD beneficiary who is not receiving care for AKI. AKI is usually a temporary loss of kidney function. If the kidney injury becomes permanent, such that the beneficiary is undergoing maintenance dialysis, then the beneficiary would be eligible for attribution.
- Has a diagnosis of dementia, because conducting dialysis at home may present an undue challenge for beneficiaries with dementia, and such beneficiaries also may not prove to be appropriate candidates for transplant.

We considered excluding beneficiaries from attribution for the purposes of calculating the home dialysis rate whose advanced age (for example, ages 70 and older) could make home dialysis inappropriate; however, we could not ascertain a consensus in the literature that supported any specific age cut-off. We also considered excluding beneficiaries with housing insecurity from attribution for the purposes of calculating the home dialysis rate, but could not find an objective way to measure housing instability.

We invite public comment on the proposed exclusions from beneficiary attribution under the ETC Model, including criteria according to which dementia should be assessed, as well as any others, for example, physical or functional limitations, on the basis of which beneficiaries should be excluded from attribution. We also seek comments as to whether we should exclude beneficiaries over a specific age threshold, and whether there is an objective measure we could use for housing insecurity.

(2) Attribution Services

(a) Attribution to ESRD Facilities

We propose that, to be attributed to an ESRD facility for a month, an ESRD beneficiary must have received renal dialysis services, other than renal dialysis services for AKI, during the month from the ESRD facility. Because it is possible that a single ESRD Beneficiary receives dialysis treatment from more than one ESRD facility during a month, we further propose that ESRD Beneficiaries would be attributed to an ESRD facility for a given month based on the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month. We believe the plurality rule would provide a sufficient standard for attribution because it ensures that ESRD Beneficiaries would be attributed to an ESRD facility when they receive more renal dialysis services from that ESRD facility than from any other ESRD facility. In the event that an ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, we propose that the ESRD Beneficiary would be attributed to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month.

We propose that we would identify dialysis claims as those with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and that have a claim through date during the month for which attribution is being determined. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. Facility code 7 paired with type of care code 2 indicates that the claim occurred at a clinic or hospital based ESRD facility.

In the alternative, we considered attributing ESRD Beneficiaries to the ESRD facility at which they had their first dialysis treatment for which a claim was submitted in a given month. However, we determined that using the plurality of claims rather than earliest claim better identifies the ESRD facility that has the most substantial care relationship with the ESRD Beneficiary in question for the given month. For example, using the earliest claim approach could result in attributing a beneficiary that received dialysis treatments from Facility A once during a given month and dialysis treatments from Facility B at all other times during that month to Facility A, even though Facility B is the facility where the beneficiary received most of his or her dialysis treatments that month. We do, however, plan to use the earliest date of service in the event that two or more ESRD facilities have furnished the same amount of services to a beneficiary because, as between two or more facilities that performed the same number of dialysis treatments for the beneficiary during a month, the facility that furnished services to the beneficiary first may have established the beneficiary's care plan and therefore is the one more likely to have the most significant treatment relationship with the beneficiary. We note that this proposed policy is consistent with the CEC Model.

We also considered using a minimum number of treatments at an ESRD facility for purposes of ESRD Beneficiary attribution. However, we determined that, because we are attributing ESRD Beneficiaries on a month-by-month basis, the plurality of treatments method would be more appropriate because it would result in a greater number of ESRD Beneficiaries attributed to the ESRD facilities where they receive care, which may enhance the viability of the ETC Model test. Additionally, we considered including a minimum duration that an ESRD

Beneficiary must be on dialysis before the beneficiary can be attributed to an ESRD facility. We determined that this approach was not suitable for this model test, however, as a key factor that influences whether or not a beneficiary chooses to dialyze at home is if the beneficiary begins dialysis at home, rather than in-center. Requiring a minimum duration on dialysis would exclude these early months of dialysis treatment from attribution, which may be key to a beneficiary's modality choice, and would therefore run counter to the intent of the proposed Model.

We propose that CMS would not attribute pre-emptive transplant beneficiaries to ESRD facilities because beneficiaries who receive pre-emptive transplants do so before they have initiated dialysis and thus do not have a care relationship with the ESRD facility.

We seek comment on the proposed methodology for attributing ESRD Beneficiaries to ESRD facilities and the alternatives considered, as well as our proposal not to attribute pre-emptive transplant beneficiaries to ESRD facilities.

(b) Attribution to Managing Clinicians

We propose that, for Managing Clinicians, an ESRD Beneficiary would be attributed to the Managing Clinician who submitted an MCP claim with a claim through date in a given month for certain services furnished to the ESRD beneficiary. Per the conditions for billing the MCP, the MCP can only be billed once per month for a given beneficiary.[128] Therefore, we believe there is no need to create a decision rule for attributing ESRD Beneficiaries to a Managing Clinician for a given month if there are multiple MCP claims that month, as that should never happen. We propose that, for purposes of ESRD Beneficiary attribution to Managing Clinicians, we would include MCP claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12–19, or 20 years of age and older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD-related services for home dialysis per full month, and indicate the age of the beneficiary (12–19, or 20 years of age and older). Taken together, these are all the CPT® codes that are used to bill the MCP that include beneficiaries 18 years old or older, including patients who dialyze at home and patients who dialyze in-center.

Additionally, for the transplant rate for Managing Clinicians, we would also attribute pre-emptive transplant beneficiaries to Managing Clinicians. Because pre-emptive transplant beneficiaries have not started dialysis at the time of their transplant, we would not be able to attribute them to Managing Clinicians based on MCP claims, as we would for ESRD Beneficiaries. Rather, we propose that pre-emptive transplant beneficiaries would be attributed to a Managing Clinician based on the Managing Clinician with whom the beneficiary had the most claims between the start of the MY and the month in which the beneficiary received the transplant, and that the pre-emptive transplant beneficiary would be attributed to the Managing Clinician for all months between the start of the MY and the month in which the beneficiary received the transplant. We considered attributing pre-emptive transplant beneficiaries on a month-by-month basis, mirroring the month-by-month attribution of ESRD Beneficiaries. However, we concluded that this approach would under-attribute beneficiary months to the denominator. Unlike ESRD Beneficiaries who see their Managing Clinician every month for dialysis management, pre-emptive transplant beneficiaries generally do not see a Managing Clinician every month because they have not started dialysis. However, that does not mean that an ongoing care relationship does not exist between the pre-emptive transplant beneficiary and the Managing Clinician in a month with no claim.

We seek comment on the proposed methodology for attributing ESRD Beneficiaries and pre-emptive transplant beneficiaries to Managing Clinicians and the alternatives considered.

c. Performance Measurement

We propose to calculate the home dialysis and transplant rates for ESRD facilities and Managing Clinicians using Medicare claims data and Medicare administrative data about beneficiaries, providers, and suppliers. Medicare administrative data refers to non-claims data that Medicare uses as part of regular operations. This includes information about beneficiaries, such as enrollment information, eligibility information, and demographic information. Medicare administrative data also refers to information about Medicare-enrolled providers and suppliers, including Medicare enrollment and eligibility information, practice and facility information, and Medicare billing information. For the transplant rate calculations, CMS also proposes to use data from the Scientific Registry of Transplant Recipients (SRTR), which contains comprehensive information about transplants that occur in the U.S., to identify transplants among attributed beneficiaries for inclusion in the numerator about the occurrence of kidney and kidney-pancreas transplants. We considered requiring ETC Participants to report on their home dialysis and transplant rates, as this would give ETC Participants more transparency into their rates. However, we believe basing the rates on claims data, supplemented with Medicare administrative data about beneficiary enrollment and transplant registry data about transplant occurrences, would ensure there is no new reporting burden on ETC Participants. Additionally, using these existing data sources would be more cost effective for CMS, as it would not require the construction and maintenance of a new reporting portal, or changes to an existing reporting portal to support this data collection.

We solicit comment on our proposed use of claims data, Medicare beneficiary enrollment data, and transplant registry data to calculate the home dialysis rate and transplant rate.

(1) Home Dialysis Rate

We propose to define ''home dialysis rate'' as the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b) (Home Dialysis Rate). We propose to construct the home dialysis rate for ETC Participants that are ESRD facilities as described in section IV.C.5.c.1.a of this proposed rule and for ETC Participants who are Managing Clinicians as described in section IV.C.5.c.1.b of this proposed rule.

We solicit comment on our proposed methodology for assessing home dialysis rates for ESRD facilities and Managing Clinicians that are ETC Participants, as well as alternative methodologies for assessing home dialysis rates. We describe later our proposed plan for risk adjusting and reliability adjusting these rates.

(a) Home Dialysis Rate for ESRD Facilities

Under our proposal, the denominator of the home dialysis rate for ESRD facilities would be the total dialysis treatment beneficiary years for

[128] Medicare Claims Processing Manual, Chapter 8; *https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf.*

attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which attributed ESRD beneficiaries received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. We would identify months during which an attributed ESRD Beneficiary received maintenance dialysis based on claims, specifically claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility, and the Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities.

We propose that the numerator of the home dialysis rate for ESRD facilities would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home. Home dialysis treatment beneficiary years included in the numerator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis at home months based on claims, specifically claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, with condition codes 74, 75, 76, or 80. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. Condition codes 74 and 75 indicate billing for a patient who received dialysis services at home, and condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. Condition code 76 indicates billing for a patient who dialyzes at home but received back-up dialysis in a facility. Taken together, we believe these condition codes capture home dialysis services furnished by ESRD facilities. Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data.

We considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center hemodialysis, making it impossible for CMS to identify the relevant claims. We seek comment on the identification and inclusion of these particular beneficiaries in the numerator of the home dialysis rate calculation for ESRD facilities.

(b) Home Dialysis Rate for Managing Clinicians

We propose that the denominator of the home dialysis rate for Managing Clinicians would be the total dialysis treatment beneficiary years for attributed ESRD beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis months based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12–19 years of age or 20 years of age and older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD related services for home dialysis per full month, and indicate the age of the beneficiary (12–19 years of age or 20 years of age and older). Taken together, these codes are used to bill the MCP for beneficiaries aged 18 or older, including patients who dialyze at home and patients who dialyze in-center.

The numerator for the home dialysis rate for Managing Clinicians would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home. Home dialysis treatment beneficiary years included in the numerator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis at home months based on claims, specifically claims with CPT® codes 90965 or 90966. CPT® code 90965 is for ESRD related services for home dialysis per full month for patients 12–19 years of age. CPT® code 90966 is for ESRD related services for home dialysis per full month for patients 20 years of age and older. These two codes are used to bill the MCP for beneficiaries aged 18 and older who dialyze at home. Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data.

We considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center hemodialysis, making it impossible for CMS to identify the relevant claims. We seek comment on the identification and inclusion of these particular beneficiaries in the numerator of the home dialysis rate calculation for Managing Clinicians.

(2) Transplant Rate

We propose to define the ''transplant rate'' as the rate of ESRD Beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC Participant who received a kidney or kidney-pancreas transplant during the MY, as described in proposed § 512.365(c) (Transplant Rate). We propose to construct the transplant rate for ETC Participants that are ESRD facilities as described in section IV.C.5.c.(2)(a) of this proposed rule, and for ETC Participants who are Managing Clinicians as described in section IV.C.5.c.(2)(b) of this proposed rule.

For purposes of constructing the transplant rate, we propose two transplant rate-specific beneficiary exclusions. Specifically, we propose to exclude an attributed beneficiary from the transplant rate calculations for any months during which the beneficiary was 75 years of age or older at any point during the month, and for any months in which the beneficiary was in a skilled nursing facility (SNF) at any point during the month. We propose these additional exclusions to recognize that, while these beneficiaries can be candidates for home dialysis, they are generally not considered candidates for transplantation. These exclusions would be similar to the exclusions used in the Percentage of Prevalent Patients Waitlisted (PPPW) measure that has been adopted by ESRD QIP. We seek comment on the proposal to exclude from the transplant rate beneficiaries aged 75 or older and beneficiaries in

SNFs. The transplant rate calculations would also exclude beneficiaries who elected hospice, as we are proposing to exclude beneficiaries who have elected hospice from attribution generally under the ETC Model and therefore they would be excluded from the calculation of both the transplant rate and the home dialysis rate.

We considered using rates of transplant waitlisting rather than the actual transplant rate. However, for the ETC Model, we propose to test the effectiveness of the Model's incentives on outcomes, rather than on processes. The relevant outcome for purposes of the ETC Model is the receipt of a kidney or kidney-pancreas transplant, not getting on and remaining on the kidney transplant waitlist. While we acknowledge that getting a beneficiary on the transplant waitlist is more directly influenced by the ESRD facility and/or the Managing Clinician than the beneficiary actually receiving the transplant, we believe that ESRD facilities and Managing Clinicians are well positioned to assist beneficiaries through the transplant process, and we want to incentivize this focus. Transplant waitlist measures also do not capture living donation, which is an additional path to a successful kidney transplant, and ESRD facilities and Managing Clinicians may support this process. Details about the PPPW Clinical Measure can be found in the CY 2019 ESRD PPS final rule (83 FR 56922, 57003–08). We solicit comment on our proposal to not test the effectiveness of the Model's incentives on increasing the number of patients added to the kidney transplant waitlist. Additionally, we solicit comment on an alternative transplant waitlist measure that would also capture living donation.

We propose using one year of data, from an MY, to construct the transplant rate to align with the construction of the home dialysis rate. However, because transplants are rare events for statistical purposes, we may not have sufficient statistical power to detect meaningful variation using only one year of performance information at the ETC Participant level. In order to ensure that we would have sufficient statistical power to detect meaningful variation in performance, we also considered the alternative of using 2, 3, or 4 years of data, corresponding with the MY plus the calendar year or years immediately prior to the MY, to construct the transplant rate. However, we wanted to avoid adjusting ETC Participant payment based on performance that occurred prior to the implementation of the ETC Model, if finalized, and concluded that the proposed reliability adjustment aggregation methodology, described in section IV.C.5.c.(4) of this proposed rule, would compensate for any lack of statistical power, and would therefore eliminate the need to include data from calendar years prior to the MY in order to produce a reliable and valid transplant rate. We solicit feedback on our proposal to construct the transplant rate using only one year of data, from the MY.

Also, we solicit comment on our proposed methodology for assessing transplant rates and alternative methodologies considered for assessing transplant rates. We discuss later in this rule our proposed plan for risk adjusting and reliability adjusting these rates.

(a) Transplant Rate for ESRD Facilities

For ESRD facilities, we propose that the denominator for the transplant rate would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, subject to the aforementioned exclusions. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year would be comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis would be identified by claims with Type of Bill 072X. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. However, in order to effectuate the exclusions previously described, we would exclude claims for attributed ESRD Beneficiaries who were 75 years of age or older at any point during the month or were in a SNF at any point during the month.

We propose that the numerator for the transplant rate for ESRD facilities would be the total number of attributed beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY. We would identify kidney and kidney-pancreas transplants using Medicare claims data, Medicare administrative data, and SRTR data. For Medicare claims data, we would use claims with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach). Because kidney-pancreas transplants are billed by including an ICD–10 procedure code for the type of kidney transplant and a separate ICD–10 procedure code for the type of pancreas transplant, we determined that we would not need to include additional ICD–10 codes to capture kidney-pancreas transplants beyond the ICD–10 codes for kidney transplants listed. We propose that we would supplement Medicare claims data on kidney and kidney-pancreas transplants with information from the SRTR Database and Medicare administrative data about the occurrence of kidney and kidney-pancreas transplants not identified through claims. If a beneficiary who receives a transplant during a MY returns to dialysis during the same MY, the beneficiary would remain in the numerator.

We also considered constructing the numerator for the ESRD facility transplant rate such that the number of attributed beneficiaries who received transplants during a MY would remain in the numerator for every MY after the transplant during which the transplanted beneficiary does not return to dialysis, for the duration of the proposed ETC Model. Keeping attributed beneficiaries who received transplants in a MY in the numerator for MYs subsequent to the MY in which the transplant occurs would acknowledge the significant efforts made by ESRD facilities to successfully assist beneficiaries through the transplant process. However, we believe this approach would artificially inflate transplant rates in later years of the Model and disproportionately disadvantage new ESRD facilities who begin providing care to ESRD beneficiaries in later years of the Model. We concluded that this potential for artificially inflated rates and the disadvantage that would result for new ESRD facilities outweighed the advantage of accruing transplants over time. We solicit comment on the inclusion of transplants in the numerator after the year of the transplant.

(b) Transplant Rate for Managing Clinicians

Whereas ESRD facilities provide care to beneficiaries only once they have

begun dialysis, Managing Clinicians provide care for beneficiaries before they begin dialysis. Therefore, we propose to use a numerator and denominator for the transplant rate for Managing Clinicians that would include pre-emptive transplant beneficiaries, that is, beneficiaries who receive transplants before beginning dialysis, in addition to ESRD Beneficiaries. In this construction, a pre-emptive transplant beneficiary would be included in the numerator for the Managing Clinician as a transplant and in the denominator for the Managing Clinician for the number of months from the beginning of the MY up to and including the month of the transplant. We considered including pre-emptive transplants during the MY among attributed pre-emptive transplant beneficiaries in the numerator, to acknowledge Managing Clinician efforts in assisting ESRD beneficiaries with pre-emptive transplants, without including them in the denominator. However, we concluded that this would disproportionately favor pre-emptive transplants in the construction of the rate. We seek comment on the proposed inclusion of pre-emptive transplants in both the numerator and the denominator for the Managing Clinician transplant rate calculation.

We propose that the denominator for the transplant rate for Managing Clinicians would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, plus the total number of attributed beneficiary years for pre-emptive transplant beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis would be identified based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD related services monthly, and indicate beneficiary age (12–19 or 20 years of age or older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD related services for home dialysis per full month, and indicate the age of the beneficiary (12–19 or 20 years of age or older). Taken together, these codes are used to bill the MCP, including patients who dialyze at home and patients who dialyze in-center. However, in order to effectuate the exclusions previously described, we would exclude claims for attributed ESRD Beneficiaries who were 75 years of age or older at any point during the month or were in a SNF at any point during the month.

For pre-emptive transplant beneficiaries, attributed beneficiary years included in the denominator would be composed of those months during which a pre-emptive transplant beneficiary is attributed to the Managing Clinician, between the start of the MY and the month of the transplant. We recognize that including pre-emptive transplant beneficiary years in the denominator may create a bias in favor of pre-emptive transplants occurring at the beginning of the MY, which may influence Managing Clinician behavior. As pre-emptive transplant beneficiaries only contribute months to the denominator from the start of the MY to the month of the transplant, the earlier in the MY the transplant occurs, the fewer months are included in the denominator, and the higher the Managing Clinician's transplant rate. However, we believe that the potential for this bias to impact Managing Clinician behavior is small due to the complexity of scheduling in the pre-emptive transplant process (such as surgeon availability, donor and recipient schedules, etc.).

We propose that the numerator for the transplant rate for Managing Clinicians would be the number of attributed ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY, plus the number of pre-emptive transplant beneficiaries attributed to the Managing Clinician for the MY. We would identify kidney and kidney-pancreas transplants using Medicare claims data, Medicare administrative data, and SRTR data. For Medicare claims data, we would use claims with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach). Because kidney-pancreas transplants are billed by including an ICD–10 procedure code for the type of kidney transplant and a separate ICD–10 procedure code for the type of pancreas transplant, we concluded that we would not need to include additional ICD–10 codes to capture kidney-pancreas transplants beyond the ICD–10 codes for kidney transplants listed. We propose that we would supplement Medicare claims data on kidney and kidney-pancreas transplants with information from the SRTR Database and Medicare administrative data about the occurrence of kidney and kidney-pancreas transplants not identified through claims. If a beneficiary who receives a transplant during an MY returns to dialysis during the same MY, the beneficiary would remain in the numerator, to acknowledge the efforts of the Managing Clinician in facilitating the transplant but also to hold the Managing Clinician harmless for transplant failure, which may be outside of the Managing Clinician's control.

We also considered constructing the numerator for the Managing Clinician transplant rate such that the number of attributed beneficiaries who received transplants during a MY would remain in the numerator for every MY after the transplant for which the transplanted beneficiary does not return to dialysis, for the duration of the ETC Model. Keeping transplants in the numerator for MYs subsequent to the MY in which the transplant occurs would acknowledge the significant efforts made by Managing Clinicians to successfully assist beneficiaries through the transplant process. However, we believe this approach would artificially inflate transplant rates in later years of the Model and disproportionately disadvantage new Managing Clinicians who begin providing care to ESRD Beneficiaries in later years of the proposed Model. We concluded that this potential for artificially inflated rates and the disadvantage that would result for new ESRD facilities outweighed the advantage of accruing transplants over time. We solicit comment on the inclusion of transplants in the numerator after the year of the transplant.

(3) Risk Adjustment

In order to account for underlying variation in the population of beneficiaries attributed to participating ESRD facilities and Managing Clinicians, we propose that CMS would risk adjust both the home dialysis rate and the transplant rate.

For the home dialysis rate, we propose to use the most recent final risk score for the beneficiary, calculated using the CMS–HCC (Hierarchical

Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program, to risk adjust the home dialysis rate under the proposed ETC Model. Internal analyses completed by CMS show that lower HCC risk scores are associated with beneficiaries on home dialysis than with beneficiaries on in-center HD. The risk adjustment methodology we are proposing for the ETC Model home dialysis rate would account for ESRD facilities and Managing Clinicians with a population that is relatively sicker than the general Medicare population. The CMS–HCC risk adjustment models were developed for the Medicare Advantage program and uses a Medicare beneficiary's medical conditions and demographic information to predict Medicare expenditures for the next year. In the Medicare Advantage context, the per-person capitation amount paid to each Medicare Advantage plan is adjusted using a risk score calculated using the CMS–HCC Models.[129] There are various CMS–HCC Models used in the Medicare Advantage program, all of which are developed using cost and diagnoses from claims data from the Medicare FFS program, including models specific to calculating risk scores for enrollees with ESRD. Under the CMS–HCC Models, the risk factors—meaning the demographic factors and conditions (as represented by HCCs)—have a coefficient that represents the amount of risk projected to be associated with and is unique to the condition or demographic status. A relative factor is created for each demographic and condition variable by dividing the coefficient by the average annual cost of a FFS beneficiary predicted by the model in a denominator year. For payment, CMS calculates a risk score for each enrollee by adding the relative factors of an enrollee's demographics and health status (that is, HCCs). CMS then multiplies the resulting risk score (after some adjustments are applied) by the monthly capitation amount to pay the Medicare Advantage plan risk adjustment. CMS has developed a separate CMS–HCC ESRD Model for beneficiaries who are on dialysis, who have received kidney transplants, or who are in post-graft status.

We propose to use the most recent final risk score calculated for the beneficiary that is available at the time of the calculation of ESRD facility and Managing Clinician home dialysis rates to risk adjust the ETC Model home dialysis rate for that MY and corresponding PPA Period. CMS proposes and adopts the CMS–HCC ESRD Dialysis Model for risk adjusting payments to Medicare Advantage organizations for a particular payment year through the Advance Notice and Rate Announcement for the Medicare Advantage program.[130] This happens the year before the payment year begins, meaning that the CMS–HCC ESRD Dialysis Model used to risk adjust payments for 2020 was adopted and announced in April 2019. However, CMS does not calculate final risk scores for a particular payment year until several months after the close of the payment year.

For MY 1 (January 1, 2020 through December 31, 2020), which corresponds to PPA Period 1 (July 1, 2021 through December 31, 2021), we are proposing in section IV.C.5.g of this proposed rule that CMS would notify ETC Participants of their PPA no later than June 1, 2021. The calculation of the PPA and component risk-adjusted home dialysis rate would occur in May 2021. As the final risk scores for payment year 2020 would not be calculated for purposes of the Medicare Advantage program until 2021, we are proposing that CMS would use the final risk scores calculated by CMS for 2019, which will happen in 2020 using the CMS–HCC ESRD Dialysis Model adopted for risk adjustment of payments for payment year 2019 to risk adjust the home dialysis rates for MY 1/PPA Period 1. CMS adopted and announced the specific CMS–HCC ESRD Dialysis Model used for payments for 2019 in the CY 2019 Rate Announcement issued in April 2018.[131] We are further proposing that CMS would use the final risk scores calculated by CMS in 2021, using the CMS–HCC ESRD Dialysis Model adopted for risk adjustment of payments for 2020, to risk adjust the home dialysis rates for MY 2 (July 1, 2020 through June 30, 2021)/PPA Period 2 (January 1, 2022 through June 30, 2022). CMS adopted and announced the specific CMS–HCC ESRD Dialysis Model used for payments for 2020 in the CY 2020 Rate Announcement issued on April 1, 2019.[132]

We believe that using risk scores developed using the CMS–HCC ESRD Dialysis Model to risk adjust the ETC Model home dialysis rate is appropriate as it can be more difficult to transition sicker beneficiaries to home dialysis, and risk adjusting the home dialysis rate using risk scores calculated using the CMS–HCC ESRD Dialysis Model would account for the relative sickness of the population of ESRD Beneficiaries attributed to each ETC Participant relative to the national benchmark. Moreover, use of the final risk scores as we are proposing means that the ETC Model would follow the same methodology and use the same coefficients for the relevant HCCs as the CMS–HCC ESRD Dialysis Model used for the prior Medicare Advantage payment year. The CMS–HCC ESRD Dialysis Model includes the risk factors outlined in § 422.308(c)(1) and (2)(ii), so those risk factors would be used in risk adjustment for the ETC Model; the risk scores used for the ETC Model would also be adjusted with the same coding pattern and normalization factors that are adopted for the CMS–HCC ESRD Dialysis Model for the relevant year. However, for the ETC Model, there would not be a frailty adjustment (for example, outlined in § 422.308(c)(4)) that is used in the Medicare Advantage program for certain special needs plans.

We also considered not applying a risk adjustment methodology to the ETC Model home dialysis rate in recognition of the limitations of existing risk adjustment methodologies to account for housing instability, which is a key factor preventing utilization of home dialysis. However, we concluded that not risk adjusting the home dialysis rate would disproportionately disadvantage ETC Participants that provide care to sicker beneficiaries.

We also considered creating a custom risk-adjustment methodology for the ETC Model based on certain factors found in the literature to affect rates of home dialysis. However, we believe that the HCC system for risk adjustment currently in use in the Medicare Advantage program would be sufficient for the purposes of this Model, without

[129] CMS. Report to Congress: Risk adjustment in Medicare Advantage. December 2018; *cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.*

[130] For example, CMS, Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter, January 30, 2019. *cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf* and CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019; *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

[131] For the CY2019 Advance Notice and Rate Announcement, specifying the CMS–HCC ESRD Dialysis Model used for payment in 2019, see: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[132] (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019; *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

the effort required to develop a new methodology.

We propose that the risk-adjustment methodologies for the home dialysis rate and transplant rate would be applied independently. We considered using the same risk adjustment strategy for both rates, however, we recognize that the risk factors that may impact the ability of an ESRD Beneficiary to successfully dialyze at home are different from the risk factors that may impact the ability of an ESRD Beneficiary or pre-emptive transplant beneficiary to receive a kidney transplant. Further, even in the Medicare Advantage program, a different CMS–HCC Model is used for beneficiaries who have received a transplant. We believe that the benefit of separate risk adjustment methodologies outweighs the additional complexity.

For the proposed ETC Model transplant rate, we wanted to use a risk adjustment methodology that aligns with a risk adjustment methodology with which ESRD facilities and Managing Clinicians are likely to be familiar and that similarly would not require development of a new and unfamiliar methodology. We believe that the methodology used for purposes of risk adjusting the PPPW satisfies these criteria and would be appropriate to apply in risk adjusting the transplant rate. Specifically, we propose that the ESRD facility and Managing Clinician transplant rates would be risk adjusted for beneficiary age, using the similar age categories, with corresponding risk coefficients, used for purposes of the PPPW measure described earlier (83 FR 57004).

Although age alone is not a contraindication to transplantation, older patients are likely to have more comorbidities and generally be more frail, thus making them potentially less suitable candidates for transplantation, and therefore some may be appropriately excluded from waitlisting for transplantation. The risk adjustment model for the PPPW contains risk coefficients specific to each of the following age categories of beneficiaries (with age computed on the last day of each reporting month): Under 15; 15–55; 56–70; and 71–74. Given that the proposed ETC Model would exclude beneficiaries under 18 from the attribution methodology used for purposes of calculating the transplant rates, we propose to use the risk coefficients calculated for the PPPW for the populations aged 18–55, 56–70, and 71–74, with age computed on the last day of each month of the MY. Transplant rates for ESRD facilities and Managing Clinicians would be adjusted to account for the relative percentage of the population of beneficiaries attributed to each ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution. Further information on the risk adjustment model used for purposes of the PPPW can be found in the PPPW Methodology Report (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Report-for-Percentage-of-Prevalent-Patients-Waitlisted.pdf*).

We considered using the risk adjustment methodology used in the Standardized Waitlist Ratio available online at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Report-for-Standardized-First-Kidney-Transplant-Waitlist-Ratio-for-Incident-Dialysis-Facilities.pdf* for risk adjusting the ETC Model transplant rate. However, we decided not to as this measure is focused only on incident beneficiaries in their first year of dialysis, rather than the broader population of beneficiaries that would be included in the ETC Model.

We considered using the CMS–HCC ESRD Transplant Model for risk adjusting the ETC Model transplant rate. However, we decided not to as the model is focused on costs once a beneficiary receives a transplant, rather than their suitability for receiving a transplant.

We solicit comment on the proposed risk adjustment methodologies and the alternatives considered.

(4) Reliability Adjustments and Aggregation

In order to overcome low reliability of the home dialysis rate and transplant rate related to small numbers of beneficiaries attributed to individual ETC Participants, we propose to employ a reliability adjustment. Under this approach, we propose using statistical modeling to make reliability adjustments such that the home dialysis rate and the transplant rate would produce reliable estimates for all ETC Participants, regardless of the number of beneficiaries for whom they provide care. We also propose this approach to improve comparisons between ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model for purposes of achievement benchmarking and scoring, described in section IV.C.5.d of this proposed rule. The proposed reliability adjustment approach would create a weighted average between the individual ETC Participant's home dialysis rate and transplant rate and the home dialysis rate and transplant rate among the ETC Participant's aggregation group (previously described), with the relative weights of the two components based on the statistical reliability of the individual ETC Participant's home dialysis rate and transplant rate, as applicable. For example, if an ETC Participant's home dialysis rate has high statistical reliability, then the ETC Participant's individual home dialysis rate would contribute a large portion of the ETC Participant's reliability-adjusted home dialysis rate and the aggregation group's home dialysis rate would contribute a small portion of the ETC Participant's reliability-adjusted home dialysis rate. We currently employ this technique in a variety of settings, including the measures used in creating hospital ratings for Hospital Compare. The advantage of using this approach is that we could use one method to produce comparable performance rates for ESRD facilities and Managing Clinicians across the size spectrum. The disadvantage of using this approach is that reliability adjusted performance rankings do not necessarily reflect absolute or observed performance, and may be difficult to interpret directly. However, we believe this approach balances the need for individualized performance assessment and incentives with the importance of reliably assessing the performance of each ETC Participant.

For Managing Clinicians, we propose that the performance on these measures would first be aggregated up to the practice level, as identified by the practice Taxpayer Identification Number (TIN) for Managing Clinicians who are in a group practice, and at the individual National Provider Identifier (NPI) level for Managing Clinicians who are not in a group practice, that is, solo practitioners. We propose to define ''TIN'' as a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1. We propose to define ''NPI'' as the standard unique health identifier used by health care providers for billing payers assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162. We propose these definitions because they are used elsewhere by the Medicare program (see 42 CFR 414.502). Performance would then be aggregated to the aggregation group level. We propose that the aggregation group for Managing Clinicians, once aggregated to the group practice or solo practitioner level, as applicable, would be all Managing Clinicians within the HRR in

which the group practice is located (for group practices) or the Managing Clinician's HRR (for solo practitioners).

For ESRD facilities, we propose that the individual unit would be the ESRD facility. We propose to define a subsidiary ESRD facility as an ESRD facility owned in whole or in part by another legal entity. We propose this definition in recognition of the structure of the dialysis market, as described in this rule. We propose that the aggregation group for subsidiary ESRD facilities would be all ESRD facilities located within the ESRD facility's HRR owned in whole or in part by the same company, and that ESRD facilities that are not subsidiary ESRD facilities would be in an aggregation group with all other ESRD facilities located within the same HRR (with the exception of those ESRD facilities that are subsidiary ESRD facilities).

We seek input on our proposal to use reliability adjustments to address reliability issues related to small numbers, as well as on our proposed aggregation groups for conducting the reliability adjustment for ESRD facilities and Managing Clinicians that are ETC Participants.

We acknowledge that for some segments of the dialysis market, companies operating ESRD facilities may operate specific ESRD facilities that focus on home dialysis, which furnish home dialysis services to all patients receiving home dialysis through that company in a given area. Therefore, assessing home dialysis rates at the individual ESRD facility level may not accurately reflect access to home dialysis for beneficiaries receiving care from a specific company in the area. We believe that the reliability adjustment approach would help to address this concern, because the construction of the reliability adjustment for subsidiary ESRD facilities would aggregate to the company level within a given HRR and thus incorporate this dynamic. We considered using a single aggregated home dialysis rate for all ESRD facilities owned in whole or in part by the same company within a given HRR to account for this market dynamic. However, we concluded that producing individual ESRD facility rates and reliability adjusting individual ESRD facility scores would be necessary to incentivize ESRD facilities within the same company in the same HRR to provide the same level of care to all of their attributed beneficiaries. We seek public comment on our proposal to address this facet of the provision of home dialysis in the larger dialysis market through the reliability adjustment as well as the alternatives considered.

d. Benchmarking and Scoring

We propose calculating two types of benchmarks for rates of home dialysis and transplants against which to assess ETC Participant performance in MY 1 and MY 2 (both of which begin in CY 2020). Risk-adjusted and reliability-adjusted ETC Participant performance for the home dialysis rate and the transplant rate would be assessed against these benchmarks on both achievement and improvement at the ETC Participant level.

The first set of benchmarks would be used in calculating an achievement score for the ETC Participant on both the home dialysis rate and the transplant rate. This set of benchmarks would be constructed based on historical rates of home dialysis and transplants in comparison geographic areas. We propose constructing the benchmarks using 12 months of data, beginning 18 months before the start of the MY and ending 6 months before the start of the MY, to allow time for claims run-out and calculation. We propose to refer to this period of time as the ''benchmark year.'' We propose using data from ESRD facilities and Managing Clinicians located in comparison geographic areas to construct these benchmarks. As an alternative, we considered using national performance rates to construct these benchmarks. However, in order to prevent the impact of the model intervention altering benchmarks for subsequent MYs, we decided against this alternative. We propose to calculate the home dialysis rate and transplant rate benchmarks for ESRD facilities and Managing Clinicians located in comparison geographic areas during the benchmark year using the same methodologies that we use to calculate the home dialysis rate and transplant rate for ESRD facilities and Managing Clinicians located in selected geographic areas during the MYs. We intend to establish the benchmarking methodology for future MYs through subsequent rulemaking.

Our intent in future MYs is to increase achievement benchmarks among ETC Participants above the rates observed in comparison geographic areas. By MY 9 and MY 10, in order to receive the maximum achievement score, we are considering that an ETC Participant would have to have a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant. We seek public comment on our intent to increase achievement benchmarks over the duration of the Model.

The second set of benchmarks would be used in calculating an improvement score for the ETC Participant on both the home dialysis rate and the transplant rate. This set of benchmarks would be constructed based on historical rates of home dialysis and transplants by the ETC Participant during the benchmark year. We propose to calculate the improvement score by comparing MY performance on the home dialysis rate and transplant rate against past ETC Participant performance to acknowledge efforts made in practice transformation to improve rates of home dialysis and transplants. However, we propose that an ETC Participant cannot attain the highest scoring level through improvement scoring. Specifically, while an ETC Participant could earn an achievement score of up to 2 points for the transplant rate and the home dialysis rate, the maximum possible improvement score is 1.5 points for each of the rates. This policy would be consistent with other CMS programs and initiatives employing similar improvement scoring methodologies, including the CEC Model.

We considered not including improvement scoring for the first two MYs, as this would mean assessing improvement in the MY against ETC Participant performance before the ETC Model would begin. However, we believe that including improvement scoring for the first two MYs is appropriate, as it acknowledges performance improvement gains while participating in the ETC Model. We seek input on the use of improvement scoring in assessing ETC Participant performance for the first two MYs. Table 13 details the proposed scoring methodology for assessment of MY 1 and MY 2 achievement scores and improvement scores on the home dialysis rate and transplant rate.

TABLE 13: PROPOSED SCORING METHODOLOGY FOR ASSESSMENT OF MEASUREMENT YEARS 1 AND 2 ACHIEVEMENT SCORES AND IMPROVEMENT SCORES ON THE HOME DIALYSIS RATE AND TRANSPLANT RATE

Achievement Score Scale for MYs 1 and 2	Points	Improvement Score Scale for MYs 1 and 2
90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	2	Not a scoring option
75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	1.5	Greater than 10% improvement relative to benchmark year rate
50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	1	Greater than 5% improvement relative to benchmark year rate
30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	0.5	Greater than 0% improvement relative to benchmark year rate
<30th Percentile of benchmark rates for comparison geographic areas during the benchmark year	0	Less than or equal to benchmark year rate

Under our proposal, the ETC Participant would receive the higher of the achievement score or improvement score for the home dialysis rate and the higher of the achievement score or improvement score for the transplant rate, which would be combined to produce the ETC Participant's Modality Performance Score (MPS). We propose the following formula for determining the MPS:

$$MPS = 2 \times (\textit{The higher of the home dialysis rate achievement or improvement score}) + (\textit{The higher of the transplant rate achievement or improvement score})$$

We propose that the home dialysis rate score would constitute two thirds of the MPS, and that the transplant rate score would constitute one third of the MPS. We considered making the home dialysis rate score and the transplant rate score equal components of the MPS, to emphasize the importance of both home dialysis and transplants as alternative renal replacement therapy modalities. However, we recognize that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers and suppliers that are part of the transplant process but are not included as participants in the ETC Model. For this reason, we are proposing that the home dialysis rate component take a greater weight than the transplant rate component of the MPS. We request comment on the proposed MPS calculation.

e. Performance Payment Adjustments

We propose that CMS would make upwards and downwards adjustments to payments for claims for dialysis and dialysis-related services, described in IV.C.5.e of this proposed rule, submitted by each ETC Participant with a claim through date during the applicable PPA period based on the ETC Participant's PPA. We propose that the magnitude of the potential positive and negative payment adjustments would increase over the PPA Periods of the ETC Model. The magnitude of the proposed PPAs are designed to be comparable to the MIPS payment adjustment factors for MIPS eligible clinicians, as described in sections IV.C.5.e.(1) and IV.C.5.e.(2) of this proposed rule. Specifically, the proposed PPAs are designed to be substantial enough to incentivize appropriate behavior without overly harming ETC Participants through reduced payments. The payment adjustments proposed for the ETC Model would start at the same 5 percent level in 2020 as the MIPS payment adjustment at 42 CFR 414.1405(c). The PPAs proposed for the ETC Model are also designed to increase over time and to be asymmetrical—with larger negative adjustments than positive adjustments—in order to create stronger financial incentives.

CMS believes that downside risk is a critical component of this Model in order to create strong incentives for behavioral change among ETC Participants. We are proposing that the negative adjustments would be greater for ESRD facilities than for Managing Clinicians, in recognition of the ESRD facilities' larger size and ability to bear downside financial risk relative to individual clinicians. We believe that the proposed exclusion of ESRD facilities that fall below the low-volume threshold described in section

IV.C.5.f.(1) of this proposed rule would ensure that only those ESRD facilities with the financial capacity to bear downside risk would be subject to application of the Facility PPA.

(1) Facility PPA

For ESRD facilities that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we propose to adjust certain payments for renal dialysis services by the Facility PPA. Specifically, we would adjust the Adjusted ESRD PPS per Treatment Base Rate for claim lines with Type of Bill 072x, where the type of facility code is 7 and the type of care code is 2, and for which the beneficiary is 18 or older for the entire month and where the claim through date is during the applicable PPA Period as described in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods). Facility code 7 paired with type of care code 2 indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X therefore captures all renal dialysis services furnished at or through ESRD facilities. As with the HDPA, we propose to apply the Facility PPA to claims where Medicare is the secondary payer. We see comment on this proposal.

The formula for determining the final ESRD PPS per treatment payment amount with the Facility PPA would be as follows:

$$\begin{aligned} &Final\ ESRD\ PPS\ Per\ Treatment\ Payment\ Amount\ with\ PPA \\ &= ((Adjusted\ ESRD\ PPS\ per\ Treatment\ Base\ Rate * Facility\ PPA) \\ &+ Training\ Add\ On + TDAPA) * ESRD\ QIP\ Factor + Outlier\ Payment \\ &* ESRD\ QIP\ Factor \end{aligned}$$

For time periods and claim lines for which both the Facility HDPA and the Facility PPA apply, the formula for determining the final ESRD PPS per treatment payment amount would be as follows:

$$\begin{aligned} &Final\ ESRD\ PPS\ Per\ Treatment\ Payment\ Amount\ with\ PPA\ and\ HDPA \\ &= ((Adjusted\ ESRD\ PPS\ per\ Treatment\ Base\ Rate * (Facility\ HDPA \\ &+ Facility\ PPA)) + Training\ Add\ On + TDAPA) * ESRD\ QIP\ Factor \\ &+ Outlier\ Payment * ESRD\ QIP\ Factor \end{aligned}$$

Table 14 depicts the proposed amounts and schedule for the Facility PPA over the ETC Model's PPA periods, which we propose to codify in proposed § 512.380.

TABLE 14: PROPOSED FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-4.0%	-4.5%	-5.0%	-6.0%	-6.5%
	≤ .5	-8.0%	-9.0%	-10.0%	-12.0%	-13.0%

As also described in section IV.C.7.a of this proposed rule, we further propose that the Facility PPA would not affect beneficiary cost sharing. Beneficiary cost sharing would instead be based on the amount that would have been paid under the ESRD PPS absent the Facility PPA.

(2) Clinician PPA

For Managing Clinicians that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we propose to adjust payments for

managing dialysis beneficiaries by the Clinician PPA. Specifically, we would adjust the amount otherwise paid under Part B with respect to the MCP claims on claim lines with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is 18 or older for the entire month and where the claim through date is during the applicable PPA Period as described in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods). CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12–19 or 20 years of age or older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD-related services for home dialysis per full month, and indicate the age of the beneficiary (12–19 or 20 years of age or older). Taken together, these codes are used to bill the MCP for ESRD-related services furnished to beneficiaries age 18 and older, including patients who dialyze at home and patients who dialyze in-center. As with the HDPA, we propose to apply the Clinician PPA to claims where Medicare is the secondary payer. We seek comment on this proposal.

Table 15 depicts the proposed amounts and schedule for the Clinician PPA over the ETC Model's PPA periods, which we propose to codify in proposed § 512.380.

TABLE 15: PROPOSED CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-3.0%	-3.5%	-4.0%	-4.5%	-5.5%
	≤ .5	-6.0%	-7.0%	-8.0%	-9.0%	-11.0%

We propose to adjust the amount otherwise paid under Part B by the Clinician PPA so that beneficiary cost sharing would not be affected by the application of the Clinician PPA. The Clinician PPA would apply only to the amount otherwise paid for the MCP absent the Clinician PPA.

We seek comment on our PPA proposals, including the proposed magnitude of and schedule for these proposed payment adjustments for both ESRD facilities and Managing Clinicians participating in the ETC Model.

f. Low-Volume Threshold Exclusions for the PPA

(1) ESRD Facilities

We propose excluding ETC Participants that are ESRD facilities that have fewer than 11 attributed beneficiary-years during a given MY from the application of the PPA during the corresponding PPA Period. Each beneficiary-year would be equivalent to 12 attributed beneficiary months, where a beneficiary month is one calendar month for which an ESRD beneficiary is attributed to an ETC Participant using the attribution methodology described at IV.C.5.b, meaning that an ESRD facility must have at least 132 total attributed beneficiary months for a MY in order to be subject to the PPA for the corresponding PPA period. Under our proposal, a beneficiary year could be comprised of attributed beneficiary months from multiple beneficiaries. We are proposing this exclusion threshold to increase statistical reliability and to exclude low-volume ESRD facilities from the application of the Facility PPA. We selected this particular threshold because it is similar to the 11 qualifying patient minimum threshold that the ESRD QIP uses for purposes of scoring certain measures during the performance period. We considered using the 11 qualifying patients threshold used for purposes of scoring some measures under the ESRD QIP, but due to differences in beneficiary attribution methodologies between the ESRD QIP and the proposed ETC Model, we concluded that using beneficiary-years was more appropriate for purposes of testing the ETC Model, as the rates proposed for the ETC Model are based on beneficiary-years.

We invite public comment on this proposal for excluding ESRD facilities with fewer than 11 attributed beneficiary-years from the application of the PPA during the applicable PPA Period, as well as the alternatives considered.

(2) Managing Clinicians

We propose excluding ETC Participants that are Managing Clinicians who fall below a specified low-volume threshold during an MY from the application of the PPA during the corresponding PPA Period. The low-volume exclusion would ensure that we would be adjusting payment based on reliable measurement of Managing Clinician performance. Managing Clinicians with sufficiently small attributed beneficiary populations may serve unique patient populations, such as children, such that we may not be able to produce statistically reliable transplant rates and home dialysis rates for these Managing Clinicians. We propose that the low-volume threshold would be set at the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinician billed the MCP during the MY. We considered using 11 beneficiary-years as the low-volume exclusion for Managing Clinicians, to mirror the proposed exclusion for ESRD facilities. However, we recognize that ESRD facilities and Managing Clinicians are different in that Managing Clinicians are more diverse, as compared to ESRD facilities, in terms of both volume of services furnished to beneficiaries related to receiving dialysis and services furnished that are not related to dialysis. Therefore, we propose using a percentile-based low-volume exclusion threshold for Managing Clinicians that would help to ensure statistical soundness while recognizing the diversity of the Managing Clinician population. In the alternative, we considered establishing the low-volume

threshold based on the bottom five percent of Managing Clinicians who are ETC Participants in the total dollar value of Medicare claims paid. However, as Managing Clinicians are in a variety of specialties and provide a wide range of services that are paid at a variety of rates, we concluded that a dollar-value threshold was not suitable for purposes of this proposed exclusion.

We invite public comment on this proposal for excluding certain Managing Clinicians from the application of the PPA during the applicable PPA Period based on our proposed low-volume threshold, as well as the alternatives considered.

g. Notification

Per the PPA schedule, we propose that payment adjustments would be made during the PPA period that begins 6 months after the end of the MY. This 6-month period would allow for three months claims run-out to account for lag in claims processing, and for CMS to calculate and validate the MPS and the corresponding PPA for each ETC Participant. After we calculate ETC Participant MPSs and PPAs, we propose to notify ETC Participants of their attributed beneficiaries, MPSs and corresponding PPAs. We propose notification of ETC Participants no later than one month before the start of the PPA Period in which the PPA would go into effect. We believe this notification period balances the need for sufficient claims run-out to ensure accuracy, as well as sufficient time for MPA and PPA calculation and validation by CMS, with our interest in providing sufficient advanced notification regarding the resulting payment adjustments to ETC Participants.

We propose to conduct notifications in a form and manner determined by CMS.

h. Targeted Review

We believe that it would be advisable to provide a process according to which an ETC Participant would be able to dispute errors that it believe to have occurred in the calculation of the MPS. Therefore, we are proposing a policy that would permit ETC Participants to contest errors found in their MPS, but not in the ETC Model home dialysis rate calculation methodology, transplant rate calculation methodology, achievement and improvement benchmarking methodology, or MPS calculation methodology. We note that, if ETC Participants have Medicare FFS claims or decisions they wish to appeal (that is, Medicare FFS issues experienced by the ETC Participant that occur during their participation in the ETC Model that do not involve the calculation of the MPS), then the ETC Participant should continue to use the standard CMS procedures through their Medicare Administrative Contractor. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims and decisions made by CMS.

We propose that ETC Participants would be able to request a targeted review of the calculation of their MPS. ETC Participants would be able to request a targeted review for certain considerations, including, but not limited to, when: The ETC Participant believes there to have occurred an error in the home dialysis rate or transplant rate used in the calculation of the MPS due to data quality or other issues; or the ETC Participant believes that there are certain errors, such as misapplication of the home dialysis rate or transplant rate benchmark in determining the ETC Participant's achievement score, improvement score, or the selection of the higher score for use in the MPS. The targeted review process would be subject to the limitations on administrative and judicial review as previously described. Specifically, an ETC Participant could not use the targeted review process to dispute a determination that is precluded from administrative and judicial review under section 1115A(d)(2) of the Act and proposed § 512.170.

To request a targeted review, the ETC Participant would provide written notice to CMS of a suspected error in the calculation of their MPS no later than 60 days after we notify ETC participants of their MPS, or at a later date as specified by CMS. We propose that this written notice must be submitted in a form and manner specified by CMS. The ETC Participant would be able to include additional information in support of its request for targeted review at the time the request is submitted.

We propose that we will respond to each request for targeted review submitted in writing in a timely manner, and determine within 60 days of receipt of the request whether a targeted review is warranted. We propose that we would either accept or deny the request for targeted review, or request additional information from the ETC Participant that we would deem necessary to make such a decision. If we were to request additional information from the ETC Participant, it would be required to be provided and received within 30 days of the request. Non-responsiveness to the request for additional information would potentially result in the closure of the targeted review request. If we were to find, after conducted a targeted review, that there had been an error in the calculation of the ETC Participant's MPS, we would notify the ETC Participant within 30 days of the finding. If the error in the MPS were such that it caused us to apply an incorrect PPA during the PPA period associated with the incorrect MPS, we would notify the ETC Participant and resolve the payment discrepancy during the next PPA period following notification of the MPS error. Decisions based on the targeted review process would be final, and there would be no further review or appeal.

We considered compressing the duration of the targeted review process such that it could be completed before the PPA period in which the MPS in question sets the PPA. However, we believe that this would be an insufficient amount of time for ETC Participants to review their MPS, consider the possibility of a calculation or data error, request a targeted review, and provide additional information to CMS if requested.

We invite public comment on these proposed provisions regarding the proposed targeted review process.

6. Overlap With Other Innovation Center Models and CMS Programs

The ETC Model would overlap with several other CMS programs and models, and we seek comment on our proposals to account for overlap:

- ESRD Quality Incentive Program (ESRD QIP)—The ESRD QIP reduces payment to a facility under the ESRD PPS for a calendar year by up to 2 percent if the facility does not meet or exceed the total performance score established by CMS for the corresponding ESRD QIP payment year with respect to measures specified for that payment year. We propose that the ETC Model's Facility HDPA and Facility PPA would be applied prior to the application of the ESRD QIP payment adjustment to the ESRD PPS per treatment payment amount, as we are proposing that the Facility HDPA and the Facility PPA would adjust the Adjusted ESRD PPS per Treatment Base Rate, as previously discussed at section IV.C.4.b of this proposed rule.
- Merit-based Incentive Payment System (MIPS)—Under section 1848(q)(6) of the Act and 42 CFR 414.1405(e), the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) generally apply to the amount

otherwise paid under Medicare Part B with respect to covered professional services furnished by a MIPS eligible clinician during the applicable MIPS payment year. We propose that the Clinician HDPA and the Clinician PPA in the ETC Model would similarly apply to the amount otherwise paid under Medicare Part B, but would occur prior to the application of the MIPS payment adjustment factors. This is designed to ensure that the MIPS payment adjustment factors will still have a significant weight for Managing Clinicians.

• Kidney Care First Model (KCF) and the Comprehensive Kidney Care Contracting (CKCC) Model—The KCF and CKCC Modela are optional Innovation Center models for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that are focused on beneficiaries with CKD and beneficiaries with ESRD. The KCF and CKCC Models will run from January 1, 2020, through December 31, 2025, and will have five years of financial accountability overlap with the ETC Model beginning January 1, 2021. We propose that the types of entities eligible to participate in these models -KCF practices and Kidney Contracting Entities (KCEs)—would be permitted to participate in either the KCF or one of the CKCC Models within regions where the ETC Model would be in effect. Not allowing these entities to participate as KCF practices or KCEs within the ETC Model's selected geographic areas would limit participation in the KCF and CKCC Models, and could prevent a sufficient number of KCF practices or KCEs from participating in the KCF and KCCC Models, such that these models would not have sufficient participation to be evaluated. CMS believes it is important to test both models in order to evaluate payment incentives inside and outside the coordinated care context. The ETC Model would allow for a broader scope of test due to its mandatory nature across half the country, while the KCF and CKCC Model will test the effects on outcomes of higher levels of risk for a self-selected group of participants. Payment adjustments under the ETC Model would be counted as expenditures for purposes of the KCF and CKCC Models. Both models would include explicit incentives for participants when beneficiaries receive kidney transplants; and a participant in both models would be eligible to receive both types of adjustments under the ETC Model (the HDPA and PPA), as well as a Kidney Transplant Bonus under the KCF and CKCC Models. Kidney transplants represent the most desired and cost effective treatment for most beneficiaries with ESRD, but providers and suppliers may currently have insufficient financial incentives to assist beneficiaries through the transplant process because dialysis generally results in higher reimbursement over a more extended period of time than a transplant.[133] As a result, CMS believes it would be appropriate to test incentives in both the ETC Model and the KCF and CKCC Models simultaneously to assess their effects on the transplant rate.

• Comprehensive ESRD Care (CEC) Model—The CEC Model is a voluntary Innovation Center model for ESRD dialysis facilities, nephrologists, and other providers and suppliers that focuses on beneficiaries with ESRD. The CEC Model will end on December 31, 2020, and therefore, would overlap for one year with the proposed ETC Model. We propose that ETC Participants could be selected from regions where there are participants in the CEC Model. Given the national distribution of CEC ESCOs, we do not believe the overlap between the two Models would impact the validity of the ETC Model test, as ESCOs would be equally likely to be located in selected geographic areas as in comparison geographic areas, creating a net neutral effect. We do not believe that the proposed ETC Model would significantly affect the CEC Model because the payment incentives under the ETC Model would be smaller in 2020 when the CEC Model is active and because the CEC Model is focused on total cost of care, the majority of which is non-dialysis care. Not allowing CEC ESCOs to participate in the CEC Model within the ETC Model's selected geographic areas would require either terminating ESCOs that participate in the CEC Model in the ETC Model's selected geographic areas, which we believe would negatively impact the CEC Model test by requiring termination of several ESCOs, or altering ETC Model randomization to exclude regions in which CEC ESCOs are participating in the CEC Model, which we believe would negatively impact the ETC Model by interfering with the proposed randomization.

• All other Medicare APMs—For other Medicare APMs, such as the Medicare Shared Savings Program or the Next Generation ACO Model, that focus on total cost of care, we propose that any increase or decrease in program expenditures that are due to the ETC Model would be counted as program expenditures to ensure that the Medicare APM continues to measure the total cost of care to the Medicare program. The Medicare Shared Savings Program regulations include a policy for addressing payments under a model, demonstration, or other time-limited program. Specifically, in conducting payment reconciliation for the Shared Savings Program, CMS considers ''individually beneficiary identifiable final payments made under a demonstration, pilot, or time limited program'' (see, for example, § 426.610(a)(6)(ii)(B)). We believe that this existing policy sufficiently addresses overlaps that would arise between the Medicare Shared Savings Program and the proposed ETC Model. CMS would review any models where this form of reconciliation may not be possible and make an assessment as to what changes, if any, may be necessary to account for the effects of testing the ETC Model. We seek public input on our proposed overlap policies.

We invite public comments on our proposals to account for overlaps with other CMS programs and models.

7. Medicare Program Waivers

We believe it is necessary and appropriate to provide additional flexibilities to ETC Participants for purposes of testing the ETC Model. The purpose of such flexibilities would be to give ETC Participants additional access to the tools necessary to ensure ESRD Beneficiaries can select their preferred treatment modality, resulting in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, suppliers, and beneficiaries.

We propose to implement these flexibilities using our waiver authority under section 1115A of the Act. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive Medicare program requirements as necessary to test models under section 1115A of the Act.

a. Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA discussed in sections IV.C.4 and IV.C.5

[133] Abecassis M, Bartlett ST, Collins AJ, Davis CL, Delmonico FL, Friedewald JJ et al. Kidney transplantation as primary therapy for end-stage renal disease: a National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/KDOQITM) conference. Clinical Journal of the American Society of Nephrology. 2008;3(2):471–80.

of this proposed rule, respectively, we believe we would need to waive certain Medicare program rules.

Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we would waive requirements of the Act for the ESRD PPS and PFS payment systems only to the extent necessary to make these payment adjustments under this proposed payment model for ETC Participants selected in accordance with CMS's proposed selection methodology. Also, we would waive the requirement in section 1881(h)(1)(A) of the Act that payments otherwise made to a provider of services or a renal dialysis facility under the system under section 1881(b)(14) of the Act for renal dialysis services be reduced by up to 2.0 percent if the provider of services or renal dialysis facility does not meet the requirements of the ESRD QIP for a payment year, as may be necessary solely for purposes of ensuring that the ESRD QIP payment reduction would be applied to ESRD PPS payments that have been adjusted by the HDPA and the PPA. In addition, we propose that the payment adjustments made under this Model, would not change beneficiary cost sharing from the regular Medicare program cost sharing for the related Part B services that were paid for beneficiaries who receive services from ETC Participants. We propose that beneficiary cost sharing be unaffected because if beneficiary cost sharing changed as a result of the HDPA and the PPA, this would create a perverse incentive in which beneficiaries would pay less to receive services from ETC Participants with lower rates of home dialysis and transplants, potentially increasing beneficiary interest in receiving care from providers and suppliers performing poorly on the rates the ETC Model intends to improve, which would run counter to the intent of the Model.

Therefore we would waive the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act to the extent that these requirements otherwise would apply to payments made under the ETC Model. We seek comment on our proposed waivers of Medicare payment requirements related to the HDPA and PPA and beneficiary cost sharing.

b. Waiver of Select KDE Benefit Requirements

We believe it is necessary for purposes of testing the ETC Model to waive select requirements of the KDE benefit authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Medicare currently covers up to 6, 1-hour sessions of KDE services for beneficiaries that have Stage IV CKD. While the KDE benefit is designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access, the uptake of this service has been low at less than 2 percent of eligible patients. CMS believes that the KDE benefit is one of the best tools to promote treatment modalities other than in-center HD and that this waiver is necessary to test ways to increase its utilization from its current low rate as part of the model test.

We propose to waive the following requirements for ETC Participants billing for KDE services:

- Currently, doctors, physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) are the only clinician types that can furnish and bill for KDE services as required by section 1861(ggg)(2)(A)(i) of the Act and its implementing regulation at 42 CFR 410.48(c)(2)(i). However, the payment for KDE is lower than a typical evaluation and management (E/M) visit, so there may be limited financial incentive for these clinician types to conduct the KDE sessions. There are various other types of health care providers that also may be well-suited to educate beneficiaries about kidney disease, such as registered dieticians and nephrology nurses. In its 2015 report on home dialysis, GAO recommended allowing other types of health care providers to perform KDE to increase uptake of the benefit.[134] We propose to waive the requirement that KDE be performed by a physician, PA, NP or CNS, to allow additional clinical staff such as dietitians and social workers to furnish the service under the direction of a Medicare-enrolled participating Managing Clinician. The staff need not be Medicare-enrolled, but would furnish these services incident to the services of a clinician authorized to bill Medicare for KDE services as specified in section 1861(ggg)(2)(B)(i). We considered also waiving the requirement under section 1861(ggg)(2)(B) of the Act and the implementing regulation at 42 CFR 410.48(c)(2)(ii) restricting ESRD facilities from billing for KDE directly, but decided not to, as we do not believe it is necessary for testing the Model. Moreover, ESRD facilities are already required to educate beneficiaries about their treatment modality options in the ESRD facility conditions for coverage at § 494.70(a)(7); and to develop and implement a plan of care that addresses the patient's modality of care, at § 494.90(a)(7).
- KDE is now covered only for Medicare beneficiaries with Stage IV CKD as required by section 1861(ggg)(1)(A) of the Act and in the implementing regulations at 42 CFR 410.48(b)(1). We understand this prevents many beneficiaries in Stage V of CKD from receiving the benefits of KDE before starting dialysis or pursuing a transplant. We hypothesize that beneficiaries with ESRD could also benefit from this education in the first 6 months after an ESRD diagnosis. While CKD Stage V and early ESRD patients' disease may be more advanced and the prospect of dialysis or transplant more certain than for patients with Stage IV CKD, there is still opportunity to improve beneficiary knowledge to ensure the best patient-centered care and outcomes. GAO recommended covering the KDE benefit for beneficiaries with Stage V CKD. [135] We propose to waive the requirement that KDE is covered only for Stage 4 CKD patients for purposes of testing the ETC Model and to permit beneficiaries with CKD Stage V and those in the first 6 months of receiving an ESRD diagnosis to receive the benefit, when billed by an ETC Participant who is a Managing Clinician.
- Under 42 CFR 410.48(d)(1), at least one of the KDE sessions must be dedicated to management of comorbidities, including delaying the need for dialysis. Because we are proposing a waiver that would extend the KDE benefit to beneficiaries with CKD Stage V and ESRD in the first 6 months of diagnosis, this KDE topic may no longer be relevant to patients who are facing a more immediate decision to commence dialysis or arrange for a kidney transplant. We propose to waive the requirement that KDE include the topic of managing comorbidities and delaying the need for dialysis under the ETC Model, when furnishing KDE to beneficiaries with CKD Stage V and ESRD. We propose further clarifying, however, that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis.

[134] United States Government Accountability Office. 2015.

[135] United States Government Accountability Office. 2015.

• Under 42 CFR 410.48(d)(5)(iii), an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment must be performed by a qualified clinician during one of the 6 sessions. This requirement presents two challenges; first that it may take away time from a session that could be dedicated exclusively to education, and second that if a beneficiary demonstrates inadequate knowledge, there may not be sufficient time in one session to address all areas in which a beneficiary might need assistance. If the outcomes assessment could be performed by qualified staff during a follow-up visit to the Managing Clinician, there would still be 6 full KDE sessions available to beneficiaries, and we believe there would be more flexibility for the qualified staff to reinforce what the beneficiary learned during the KDE sessions and fill in any gaps. We propose to maintain the requirement that an outcomes assessment be performed by qualified staff in some manner within one month of the final KDE session, but to waive the requirement that it be conducted within a KDE session.

We also considered waiving the co-insurance requirement for the KDE benefit and certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites, but did not believe those waivers were necessary for purposes of testing the Model.

We seek comment on our proposals to waive select requirements of the KDE benefit for purposes of testing the ETC Model and alternatives considered.

8. Compliance With Fraud and Abuse Laws

The authority for the ETC Model is section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and certain provisions of section 1934 as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). For this Model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the SSA. However, no fraud and abuse waivers are being issued for this Model. Thus, notwithstanding any other provision of this proposed regulation, all ETC Participants must comply with all applicable laws and regulations.

9. Beneficiary Protections

As we discuss in section IV.C.4.b, we propose to attribute non-excluded ESRD Beneficiaries and, as applicable, pre-emptive transplant beneficiaries to the ETC Participant that furnishes the plurality of the beneficiary's dialysis and other ESRD-related services. Although the ETC Model would not allow ESRD Beneficiaries to opt out of the payment adjustment methodology being applied to the Medicare payments made for their care, the Model would not affect beneficiaries' freedom to choose their dialysis services provider or supplier, meaning that beneficiaries may elect to see any Medicare-enrolled provider or supplier including those selected and not selected to participate in the Model based on geography. In addition, the general beneficiary protections described in section II.B.2.a.(8) of this proposed rule would apply to the ETC Model; accordingly, ETC Participants would be prohibited from restricting beneficiary freedom of choice or access to medically necessary covered services, which includes the beneficiary's choice regarding the appropriate modality to receive covered services. ETC Participants also would be prohibited from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. We propose to prohibit ETC Participants from offering or paying any remuneration to influence a beneficiary's choice of renal replacement modality, unless such remuneration complies with all applicable law. We believe this policy is necessary to help ensure that beneficiary modality selection is based on the care of the beneficiary and the beneficiary's needs and preferences, rather than financial or other incentives the beneficiary may have received or been offered.

Furthermore, beneficiaries with disabilities who receive care from ETC Participants, including dementia and cognitive impairments, remain protected under Federal disability rights laws including, but not limited to, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, as amended, and section 1557 of the Patient Protection and Affordable Care Act. These beneficiaries cannot be denied access to home dialysis or kidney transplant due to their disability. ETC Participants may not apply eligibility criteria for participation in programs, activities, and services that screen out or tend to screen out individuals with disabilities; nor may ETC Participants provide services or benefits to individuals with disabilities through programs that are separate or different, excepting those separate programs that are necessary to ensure that the benefits and services are equally effective.

In addition, as described previously in sections IV.C.4.c and IV.C.5.e.(2) of this proposed rule, we are proposing to apply the Clinician HDPA and the Clinician PPA to the amount otherwise paid under Medicare Part B and furnished by the Managing Clinician during the CY subject to adjustment, which would mean that beneficiary cost sharing would not be affected by the application of the Clinician HDPA and the Clinician PPA. Similarly, as described in section IV.C.7.a. of this proposed rule, we intend to use our waiver authority under section 1115A(d)(1) of the Act to issue certain payment waivers, in accordance with, which beneficiaries would be held harmless from any model-specific payment adjustments made to Medicare payments under this Model.

In proposed § 512.330(a), we would require ETC Participants to prominently display informational materials in each of their offices or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. This notification would serve to inform a beneficiary that his or her provider or supplier is participating in a model that incentivizes the use of home dialysis and kidney transplants and who to contact if they have questions or concerns. We are proposing this notification to further non-speculative government interests including transparency and beneficiary freedom of choice. So as not to be unduly burdensome, CMS intends to provide a template for these materials to ETC Participants, which would identify required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content. This template would include information for beneficiaries about how to contact the ESRD Network Organizations with any questions or concerns regarding participation in the ETC Model by their health care provider(s). (The 18 ESRD Network Organizations serve distinct geographical regions and operate under contract to CMS; their responsibilities include oversight of the quality of care to ESRD patients, the collection of data to administer the national Medicare ESRD program, and the provision of technical assistance to ESRD providers and patients in areas related to ESRD). All other ETC Participant

communications with beneficiaries that are descriptive model materials and activities would be subject to the requirements for such materials and activities included in the general provisions, as discussed in section II.D.3 of this proposed rule.

We invite public comment on the proposed beneficiary protections for the ETC Model.

10. Monitoring

a. Monitoring Activities

If finalized, the general provisions relating to monitoring proposed in section II.I of this rule would apply to ETC Participants, including but not limited to cooperating with the model monitoring activities per the proposed § 512.150, granting the government the right to audit per the proposed § 512.135(a), and retaining and providing access to records per § 512.135(c) and § 512.135(b), respectively. CMS would conduct the model monitoring activities in accordance with the proposed § 512.150. We believe that we must closely monitor the implementation and outcomes of the ETC Model throughout its duration. The purpose of monitoring would be to ensure that the Model is implemented safely and appropriately; that ETC Participants comply with all the terms and conditions of the ETC Model; and to protect beneficiaries from potential harms that may result from the activities of an ETC Participant. All monitoring activities under the ETC Model would focus exclusively on Medicare FFS beneficiaries.

Consistent with proposed § 512.150, we propose that monitoring activities may include documentation requests sent to the ETC Participant; audits of claims data, quality measures, medical records, and other data from the ETC Participant; interviews with members of the staff and leadership of the ETC Participant; interviews with beneficiaries and their caregivers; site visits to the ETC Participant; monitoring quality outcomes and clinical data; and tracking patient complaints and appeals. Specific to the ETC Model, we would use the most recent claims data available to track utilization of certain types of treatments, beneficiary hospitalization and Emergency Department use, and beneficiary referral patterns to make sure the utilization and beneficiary outcomes are in line with the Model's intent. We believe this type of monitoring is important because as ETC Participants adapt to new payment incentives, we want to ensure to the greatest extent possible that the Model is effective and Medicare beneficiaries continue to receive high-quality, low cost, and medically appropriate care.

We recognize that one of the likely outcomes of this Model would be an increase in utilization of home dialysis, however, in testing payment incentives aimed at increasing utilization of this modality there may be a risk of inappropriate steering of ESRD Beneficiaries who are unsuitable for home dialysis. Therefore, to avoid inappropriate use of home dialysis, as described in section IV.C.5.c.(3) of this proposed rule, we propose to use risk adjustment to account for factors related to good candidacy for home dialysis. As described in section IV.C.5.b.(1) of this proposed rule, we also propose to exclude from beneficiary attribution certain categories of beneficiaries not well suited to home dialysis, including beneficiaries with a diagnosis of dementia. We are proposing these eligibility criteria to exclude certain categories of beneficiaries from attribution up front so Managing Clinicians and ESRD facilities that are ETC Participants do not attempt or believe that it is wise to attempt to place these particular beneficiaries on home dialysis. In addition, CMS would monitor for inappropriate encouragement or recommendations for home dialysis through the proposed monitoring activities. Instances of inappropriate home dialysis may show up in increased patient hospitalization, infection, or incidence of peritonitis. For example, multiple incidences of peritonitis would be a good indicator that the patient should not be on PD. If claims data show unusual patterns, we propose to review a sample of medical records for indicators that a beneficiary was not suited for home dialysis. Through patient surveys and interviews, CMS would look for instances of coercion on beneficiary choice of modality against beneficiary wishes. If such instances of coercion were found, we would take one or more remedial action(s) as described at proposed § 512.160 against the ETC Participant and refer the case to CMS for further investigation and/or remedial action.

Additionally, we would employ longer-term analytic strategies to confirm our ongoing analyses and detect more subtle or hard-to-determine changes in care delivery and beneficiary outcomes. Some determinations of beneficiary outcomes or changes in treatment delivery patterns may not be able to be built into ongoing claims analytic efforts and may require longer-term study. We believe it is important to monitor the transplant and home dialysis trends over a longer period of time to make sure the incentives are not adversely affecting the population of beneficiaries included in the Model.

We also would be examining the extent of any unintended consequences, including any increase in adverse clinical events such as graft failures, returns to dialysis, peritonitis and other health incidents due to home dialysis, fluctuations in machine and supplies markets, lemon-dropping clinically complex patients, cherry-picking of less clinically complex patients, increase in referrals to home dialysis for patients that are not physically or cognitively able to safely handle the responsibility of dialyzing at home, or an increase in referrals to comparison geographic areas. Specifically we would monitor the rate at which back-up in-center dialysis (Claim Code 76) and ESRD self-care retraining (Claim Code 87) are used for home dialysis beneficiaries. The use of back-up dialysis for a home dialysis beneficiary can also be an indicator of equipment malfunction. Under the Innovation Center's authority in 42 CFR 403.1110, and built upon in the proposed § 512.130, we would seek to obtain clinical data for home dialysis patients such as an increase in instances of fever, abnormal bleeding, access point issues, and changes in vitals or weight, from ETC Participants for monitoring purposes and also would use applicable Medicare claims data.

We welcome input about how to best track issues with home dialysis equipment and machines and the format of any proposed documentation for any incidents that occur, and how CMS should share any information about incidents that occur.

For those beneficiaries attributed to ETC Participants who have received a kidney transplant, we would monitor transplant registry data from the SRTR, Medicare claims data available for life of transplant, post-transplant rates of hospitalization and ED visits, infection and rejection rates, and cost of care compared to the beneficiaries who have received a kidney transplant and are not included in the ETC Model test.

A key pillar of our monitoring strategy for both transplant, pre-emptive transplant and home dialysis beneficiaries would be stakeholder engagement, and we would continue conversations and relationships with patient-advocate groups and closely monitor patient surveys to uncover any of the unintended consequences listed earlier or others that may be unforeseen. We believe beneficiary and/or care partner feedback would be a tremendous asset to help CMS determine and resolve any issues directly affecting beneficiaries.

In addition, we are seeking comment on how the proposed payment adjustments under the ETC Model may influence delivery-oriented interventions among participating ESRD facilities and Managing Clinicians (for example, increased Managing Clinician knowledge of dialysis modalities, greater patient education, increased investment in equipment and supplies), as well as how the Model's financial incentives may affect the resourcing of these endeavors, and what are the barriers to change.

We invite public comment on our proposed monitoring plan for the ETC Model.

b. Quality Measures

In addition to the monitoring activities discussed previously, we propose two ESRD facility quality measures for the ETC Model:

- Standardized Mortality Ratio (SMR); NQF #0369—Risk-adjusted standardized mortality ratio of the number of observed deaths to the number of expected deaths for patients at the ESRD facility.
- Standardized Hospitalization Ratio (SHR); NQF #1463—Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for patients at the ESRD facility.

SMR and SHR measures are currently calculated and displayed on Dialysis Facility Compare, a public reporting tool maintained by CMS. The SHR is also included in the ESRD QIP measure set as a clinical measure on which ESRD facilities' performance is scored.[136] Because data collection and measure reporting are ongoing, there would be no additional burden to ETC Participants to report data on these measures for the ETC Model. Though CMS has in a previous rule acknowledged concerns that the SMR might not be adequately risk adjusted (78 FR 72208), we believe this measure is appropriate for purposes of the ETC Model, under which the SMR would not be used for purposes of determining payment. Mortality is a key health care outcome used to assess quality of care in different settings. While we recognize that the ESRD population is inherently at high risk for mortality, we believe that mortality rates are susceptible to the quality of care provided by dialysis facilities, and note that the measure is currently being used in the CEC Model. The SMR is NQF endorsed, indicating that it serves as a reliable and valid measure of mortality among ESRD beneficiaries who receive dialysis at ESRD facilities.

We considered including the In-Center Hemodialysis (ICH) CAHPS® survey to monitor beneficiary perceptions of changes in quality of care as a result of the ETC Model. However, the ICH CAHPS survey includes only beneficiaries who receive in-center dialysis. The survey specifically excludes the two beneficiary populations that the ETC Model would focus on, namely beneficiaries who dialyze at home and beneficiaries who receive transplants and, therefore, we are not proposing to use this measure for purposes of the ETC Model.

We considered including quality measures for Managing Clinicians that are reported by Managing Clinicians for MIPS or other CMS programs. However, whereas all ESRD facilities are subject to the same set of quality measures under the ESRD QIP, there is no analogous source of quality measure data for Managing Clinicians. Managing Clinicians may be subject to MIPS, or they may be participating in a different CMS program—or an Advanced APM—which has different quality requirements. In addition, most Managing Clinicians participating in MIPS select the quality measures on which they report. Taken together, these factors mean that we would be unable to ensure that all Managing Clinicians in the ETC Model are already reporting on a given quality measure, and therefore would be unable to compare quality performance across all Managing Clinicians without imposing additional burden.

We propose that the SHR and SMR measures would not be tied to payment under the ETC Model. However, we believe that the collection and monitoring of these measures would be important to guard against adverse events or decreases in quality of care that may occur as a result of the performance-based payment adjustments in the ETC Model. We believe we would be able to observe changes over time in individual ESRD facility level scores on these measures, as well as comparing change over time for ESRD facilities that are ETC Participants against change over time in those that are not ETC Participants. In the aggregate, these measures should capture any increase in adverse events, particularly for patients on home dialysis, as home dialysis patients are included in both the numerators and denominators of these measures. Home dialysis patients primarily receive care through ESRD facilities, and barring beneficiaries excluded from the measures per the measure specifications, the majority of ESRD Beneficiaries attributed to an ETC Participant would be captured in these measures. These measures also include ESRD Beneficiaries before they receive a kidney transplant; however, beneficiaries post-transplant would not be included, per the measure specifications.

We invite public comment on the proposed quality measures and whether their proposed use would enable CMS to sufficiently monitor for adverse events for ESRD beneficiaries, in combination with the monitoring activities previously described. We also invite other suggestions as to measures that would support monitoring beneficiary health and safety under the model, while minimizing provider burden.

We also invite public comment on the proposal not to tie quality measurement to the payment adjustments in the ETC Model.

Additionally, as described in section IV.C.6 of this proposed rule, we propose that ETC Participants that are ESRD facilities would still be included in the ESRD QIP and required to comply with that program's requirements, including being subject to a sliding scale payment reduction if an ESRD facility's total performance score does not meet or exceed the minimum total performance score specified by CMS for the payment year. ETC Participants who are Managing Clinicians and are MIPS eligible clinicians would still be subject to MIPS requirements and payment adjustment factors, and those in a MIPS APM would be scored using the APM scoring standard. ETC Participants who are Managing Clinicians and who are in an Advanced APM would still be assessed to determine whether they are Qualifying APM Participants (QPs) who, as such, would earn the APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment. We do not propose to waive any of these requirements for purposes of testing the ETC Model.

11. Evaluation

An evaluation of the ETC Model would be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center. We believe an independent evaluation of the Model is necessary to understand its impacts of the Model on quality of care and Medicare program expenditures and to share with the public. We would select an independent

[136] For the specifications for these measures, see ''CMS ESRD Measures Manual for the 2018 Performance Period/2020 Payment Year'', June 20, 2018, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRD-Manual-v30.pdf.*

evaluation contractor to perform this evaluation. As specified in section II.E of this rule, all ETC Participants will be required to cooperate with the evaluation.

Research questions addressed in the evaluation would include, but would not be limited to, whether or not the ETC Model results in a higher rate of transplantation and home dialysis, better quality of care and quality of life, and reduced utilization and expenditures for beneficiaries in selected geographic areas in relation to comparison geographic areas. The evaluation would also explore qualitatively what changes Managing Clinicians and ESRD facilities implemented in response to the ETC Model, what challenges they faced, and lessons learned to inform future policy developments.

We propose that the ETC Model evaluation would employ a mixed-methods approach using quantitative and qualitative data to measure both the impact of the Model and implementation effectiveness. The impact analysis would examine the effect of the ETC Model on key outcomes, including improved quality of care and quality of life, and decreased Medicare expenditures and utilization. The implementation component of the evaluation would describe and assess how ETC Participants implement the Model, including barriers to and facilitators of change. Findings from both the impact analysis and the implementation assessment would be synthesized to provide insight into what worked and why, and to inform the Secretary's potential decision regarding model expansion.

We would use multi-pronged data collection efforts to gather the quantitative and qualitative data needed to understand the context of the Model implemented at participating ESRD facility and Managing Clinician locations and the perspectives of different stakeholders. Data for the analyses would come from sources including, but not limited to, payment and performance data files, administrative transplant registry data, beneficiary focus groups, and interviews with ETC Participants.

The quantitative impact analysis would compare performance and outcome measures over time, using a difference-in-differences or a similar approach to compare beneficiaries treated by ETC Participants to those treated by ESRD facilities and Managing Clinicians in comparison geographic areas. We would examine both cumulative and year-over-year impacts. The quantitative analyses conducted for the evaluation would take advantage of the mandatory nature of the ETC Model for ESRD facilities and Managing Clinicians located in selected geographic areas.

While the model design would control for the selection bias inherent in voluntary models, a comparison group would still be necessary to determine if any changes in outcomes are due to the ETC Model or to secular trends in CKD and ESRD care. The comparison group would be those Managing Clinicians and ESRD facilities located in comparison geographic areas which would not be subject to the ETC Model payment adjustments. The evaluator would match Managing Clinicians and ESRD facilities located in comparison geographic areas with Managing Clinicians and ESRD facilities that are located in selected geographic areas (that is, ETC Participants) using propensity scores or other accepted statistical techniques. Beneficiaries who receive care from ESRD facilities and Managing Clinicians in these selected geographic areas and comparison geographic areas would be identified using the ETC Model claims-based eligibility criteria, and would be attributed using the same claims-based beneficiary attribution methods we propose to use for purposes of calculating the MPS.

The evaluation would account for any interaction with other CKD- and ESRD-related initiatives at CMS, such as the ESRD QIP, the CEC Model, and the KCF Model, and the CKCC Models. For example, the evaluator would look for disparate outcomes that could arise in the ESRD QIP between facilities that are also participating in the ETC Model and facilities that are not participating in the ETC Model and also assess whether performance in the ETC Model varies for Managing Clinicians and ESRD Facilities who are also participating in the CEC, KCF, or CKCC Models.

We invite public comment on our proposed approach related to the evaluation of the proposed ETC Model.

12. Learning System

In conjunction with the proposed ETC Model, CMS intends to operate a voluntary learning system focused on increasing the availability of deceased donor kidneys for transplantation. The learning system would work with, regularly convene, and support ETC Participants and other stakeholders required for successful kidney transplantation, such as transplant centers, organ procurement organizations (OPOs), and large donor hospitals. These ETC Participants and stakeholders would utilize learning and quality improvement techniques to systematically spread the best practices of highest performers. The application of broad scale learning and other mechanisms for rapid and effective transfer of knowledge within a learning network would also be used. Quality improvement approaches would be employed to improve performance by collecting and analyzing data to identify the highest performers, and to help others to test, adapt and spread the best practices of these high performers throughout the entire national organ recovery system. We believe that the implementation of the learning system would help to increase the supply of transplantable kidneys, which would help ETC Participants achieve the goals of the Model.

13. Remedial Action

The remedial actions outlined in the general provisions in proposed § 512.160, if finalized, would apply to the ETC Model. Accordingly, if CMS determines that an ETC Participant has engaged in one or more of the actions listed under proposed § 512.160(a) (Grounds for Remedial Action), CMS may take one or more of the remedial actions listed under proposed § 512.160(b).

14. Termination of the ETC Model

If finalized, the general provisions relating to termination of the Model by CMS proposed in section II.J of this proposed rule would apply to the ETC Model. Consistent with these provisions, in the event we terminate the ETC Model, we would provide written notice to ETC Participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act and proposed § 512.170, termination of the Model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

V. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing, evaluation, and expansion of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated information collection requirements in section VII.C.4 of the Regulatory Impact Analysis.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

We have examined the impact of this proposed rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of proposed rules. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, reflects the economic impact of the policies contained in this proposed rule.

A. Statement of Need

1. Need for Proposed Radiation Oncology (RO) Model

Radiotherapy (RT) services represent a promising area of health care for payment and service delivery reform. First, RT services can be furnished in both freestanding radiation therapy centers paid under the Medicare Physician Fee Schedule (PFS) and the Outpatient Prospective Payment System (OPPS). There are site-of-service payment differentials between the OPPS and PFS payment systems, which can result in financial incentives to offer care in one setting over another. Second, as in other health care settings, health care providers are financially incentivized to provide more services to patients because they are paid based on the volume of care they provide, not value. We believe that these incentives are misaligned with evidence-based practice, which is moving toward furnishing fewer radiation treatments for certain cancer types. Third, difficulties in coding and setting payment rates for RT services have led to volatility in Medicare payment for these services under the MPFS and increased coding complexity and administrative burden. As part of the RO Model's design, CMS would also examine whether the model leads to higher quality care by encouraging improved adherence to clinical guidelines and by collecting information related to quality performance and clinical practice. The RO Model would incentivize RO participants to maintain high quality care with the opportunity to earn back a withheld payment amount through successful quality outcomes and clinical data reporting.

As described in detail in section III.C.8. of this proposed rule, RO participants would be required to collect and submit data on quality measures, clinical data, and patient experience throughout the course of the RO Model, beginning January 1, 2020, with the final data submission ending in 2025.

2. Need for Proposed End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model

Beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. One of CMS' goals in designing the ETC Model is to test ways to incentivize home dialysis and kidney transplants, so as to enhance beneficiary choice of modality for renal replacement therapy, and improve quality of care and quality of life while reducing Medicare program expenditures. The substantially higher expenditures, mortality, and hospitalization rates for dialysis patients in the U.S. compared to those for individuals with ESRD in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. We anticipate improvement in quality of care for beneficiaries and reduced expenditures under the ETC Model inasmuch as the Model would create incentives for beneficiaries, along with their families and caregivers, to choose the optimal kidney replacement modality.

In section IV.B of this proposed rule, we describe how current Medicare payment rules and a deficit in beneficiary education result in a bias toward in-center hemodialysis, which is often not preferred by patients or physicians relative to home dialysis or kidney transplantation. We provide evidence from published literature to support the projection that higher rates of home dialysis and kidney transplants would reduce Medicare expenditures, and, not only enhance beneficiary choice, independence, and quality of life, but also preserve or enhance the quality of care for ESRD beneficiaries.

As described in detail in sections II. and IV. of this proposed rule, ETC Participants would receive adjusted payments and would be required to comply with certain requirements, including to cooperate with CMS's monitoring and evaluation activities, for the duration of the ETC Model.

3. Impact of Proposed RO Model and ETC Model

As detailed in Table 16A, we estimate a net impact of $260 million to the Medicare program due to the RO Model from January 1 2020 through December 31 2024, with a range of impacts between $50 million and $460 million in net Medicare savings. Alternatively, as detailed in Table 16B, we estimate a net impact of $250 million to the Medicare program due to the RO Model from April 1 2020 through December 31 2024, with a range of impacts between $40 million and $450 million in net Medicare savings.

As detailed in Table 17, we estimate the Medicare program would save a net total of $185 million from the PPA and HDPA, which would be applied under the ETC Model between January 1, 2020 through June 30, 2026. We also expect that the ETC Model would cost an additional $15 million, resulting from increases in education and training costs. Therefore, the net impact to Medicare spending is estimated to be $169 million in savings as a result of the ETC Model.

We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

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 one 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. As stated previously, this proposed rule triggers these criteria.

C. Anticipated Effects

1. Scale of the Model

There is no one-size-fits-all approach to designing, implementing, and evaluating models. Each payment and service delivery model tested by the Innovation Center is unique in its goals, and thus its design. Models vary in size in order to accommodate various design features and satisfy a variety of priorities. Decisions made regarding the features and design of the model strongly influence the extent to which the evaluation will be able to accurately assess the effect of a given model test and produce clear and replicable results.

The Innovation Center conducts analyses to determine the ideal number of participants for each model for evaluation purposes. This analysis considers a variety of factors including the target population (for example, Medicare beneficiaries with select medical conditions), model eligibility (for example, beneficiary eligibility criteria for inclusion in the model), participant enrollment strategy (for example, mandatory versus voluntary) and, the need to test effects on subgroups. Model size can also be influenced by the type and size of hypothesized effect on beneficiary outcomes, such as quality of care, or the target level of model savings. The smaller the expected impact a model is hypothesized to achieve, the larger a model needs to be to have confidence in the observed impacts.

An insufficient number of participants increases the risk that the evaluation will be imprecise in detecting the true effect of a model, potentially leading, for example, to a false negative or false positive result. The goal is to design a model that is sufficiently large enough to achieve adequate precision but not so large as to waste CMS's limited resources. These decisions affect the quality of evidence CMS is able to present regarding the impacts of a model on quality of care, utilization, and spending.

a. Radiation Oncology (RO) Model

In the case of the RO Model, we determined the sample size necessary for a minimum estimated savings impact of three percent. While a savings higher than three percent would require a smaller sample size from an evaluation perspective, if we were to reduce the size of the RO Model and if the actual savings are at or just below the three percent level, then we would increase the risk of missing an opportunity to detect the actual savings produced by the Model or of concluding there are savings when there are not savings.

The RO Model as proposed would include 40 percent of radiation oncology episodes in eligible geographic areas, as defined in this proposed rule. In a simulation, we randomly selected CBSAs and found that there would be 616 physician group practices (PGPs) (325 being freestanding radiation therapy centers) and 541 hospital outpatient departments furnishing RT services in those simulated selected CBSAs. Among the simulated selected PGPs, 173 furnish RT services in both freestanding radiation therapy centers and HOPDs. 285 PGPs furnish RT services only in HOPDs, and 158 PGPs furnish RT services only in freestanding radiation therapy services. These providers and suppliers furnished 39.7 percent of radiation oncology episodes nationally, based on data from 2015 to 2017. If finalized as proposed with the Model starting in January 2020, thee RO Model would have a 5-year performance period and include an estimated 364,000 episodes, 322,000 beneficiaries, and $5.4 billion in total episode spending of allowed charges (inclusive of beneficiary cost-sharing). See Table 16A for an annual breakdown. If finalized as proposed, with an April 1, 2020 start date, the RO Model would have a 5-year performance period and include an estimated 346,000 episodes, 307,000 beneficiaries, and $5.1 billion in total episode spending of allowed charges (inclusive of beneficiary cost-sharing). See Table 16B for an annual breakdown.

b. End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model

The ETC Model as proposed would include approximately 50 percent of ESRD Beneficiaries, through the ESRD facilities and Managing Clinicians selected for participation in the Model. The Innovation Center would randomly select 50 percent of HRRs, stratified by region, and include separate from randomization all HRRs for which at least 20 percent of the component zip codes are located in Maryland. All ESRD facilities and Managing Clinicians in selected HRRs, referred to as selected geographic areas, would be required to participate in the Model. There are currently 7,097 ESRD facilities and 7,283 Managing Clinicians enrolled in Medicare, distributed across 306 HRRs and providing care for 432,436 ESRD Beneficiaries that meet the eligibility criteria for attribution to ETC Participants under the Model. Only approximately 10 percent of beneficiaries on dialysis received home dialysis in 2017. The ETC Model would apply the payment adjustments described in section IV. of this proposed rule to claims with claim through dates between January 1, 2020 through June 30, 2026, and over that time period, would include an estimated 3,548 ESRD facilities, 3,642 Managing Clinicians, 216,218 beneficiaries, and $169 million in net Medicare savings. See Table 17 for an annual breakdown.

c. Aggregate Effects on the Market

There may be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of these models, if finalized. Testing changes in Medicare payment policy may have implications for non-Medicare payers. As an example, non-Medicare patients may benefit if participating providers and suppliers introduce system-wide changes that improve the coordination and quality of health care. Other payers may also be developing payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS' evaluations of payment models. Because it is unclear whether and how this evidence applies to a test of these new payment models, our analyses assume that spillover effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We welcome comments on this assumption and evidence on how this rulemaking, if finalized, would impact non-Medicare payers and patients.

2. Effects on the Medicare Program

a. Radiation Oncology Model

(1) Overview

Under the current FFS payment system, RT services are paid on a per

service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The proposed RO Model would be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during episodes initiated between January 1, 2020 and December 31, 2024.

The proposed RO Model would test differences in payment from traditional FFS Medicare by paying model participants two equal lump-sum payments, once at the start of the episode and again at the end, for episodes of care. Episodes would be defined as all Medicare items and services described in proposed § 512.235 that are furnished to a beneficiary described in proposed § 512.215 during the period of time that begins with episode initiation defined in proposed § 512.245 and ends 89 days after the start date of the episode. Once an episode is initiated, RO participants would no longer be allowed to separately bill other HCPCS codes or APC codes for activities related to radiation treatment for the RO beneficiary in that episode.

For each participating entity, the participant-specific professional payment and participant-specific technical episode payment amounts would be determined as described in detail in section III.C.6. of this proposed rule.

The RO Model would not be a total cost of care model. RO participants would still bill traditional FFS Medicare for services not included in the episode payment and, in some instances, for less common cancers not included in the model and other exclusion criteria. A list of cancer types that meet the proposed criteria for inclusion in the RO Model and associated FFS procedure codes are included in section III.C.5. of this proposed rule.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the proposed RO Model relative to baseline expenditures. The simulation relied upon statistical assumptions derived from retrospectively constructed RT episodes between 2015 and 2017. This information was reviewed and determined to be reasonable for the estimates.

To project baseline expenditures, traditional FFS payment system billing patterns are assumed to continue under current law. Forecasts of the Medicare Part A and Part B deductibles were obtained from the 2018 Medicare Trustees Report and applied to simulated episode payments. In addition, current relative value units under the PFS and relative payment weights under the OPPS are assumed to be fixed at the simulated levels found in the 2015 through 2017 ARC episode data.

Similarly, conversion factors in both the PFS and OPPS were indexed to the appropriate update factors under current law. Payment rate updates to future PFS conversion factors are legislated at 0.25 percent in 2019 and 0.0 percent for 2020 through 2024 under the Medicare Access and CHIP Reauthorization Act of 2015. OPPS conversion factors are assumed to be updated at the Hospital Market Basket less Multifactor Productivity in our simulation. We forecast that net OPPS updates would outpace the PFS by 3.0 percent on average annually between 2019 and 2024.

(3) Medicare Estimate

Table 16 summarizes the estimated impact of the proposed RO Model. We estimate that on net the Medicare program would save $260 million ($250 million with an April 1 start date) over the 5 performance years (2020 through 2024) with final data submission of clinical data elements and quality measures in 2025 to account for episodes ending in 2024. This is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects.

We project that 82 percent of physician participants (measured by unique NPI) would receive the APM incentive payment under the Quality Payment Program at some point (at least one QP Performance Period) during the model performance period. This assumption is based on applying the 2019 QPP final rule qualification criteria to simulated billing and treatment patterns for each QPP performance year during the RO model test. Episode-initiating physicians were assumed to form an APM entity with the TIN(s) under which they bill for RT services. For each APM entity, counts of total treated patients and spending for covered physician services under the RO Model were estimated and applied to QPP qualification criteria based on CY2017 provider billing patterns.

As proposed, the APM incentive payment would apply only to the professional episode payment amounts and not the technical episode payment amounts. We also assume HOPD line item cap as described in section 1833(t)(8)(C)(i) of the Act will continue to be applied as is done under current law.

Complete information regarding the data sources and underlying methodology for withhold reconciliation were not available at the time of this forecast. In the case of the incomplete payment withhold, we assume CMS retains payment only in the event that offsetting payment errors were made elsewhere. Past CMS experience in other value based payment initiatives that included a penalty for not reporting have shown high rates of reporting compliance. Given the limited spending being withheld, scoring criteria, and specified timeframes involved, we assume that quality and patient experience withholds, on net, have a negligible financial impact to CMS. In Table 16, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. No APM incentive payments would be paid based on participation in the RO Model in 2020 and 2021, due to the two-year lag between the QP performance and payment periods.

TABLE 16A. PROPOSED ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR PROPOSED RADIATION ONCOLOGY MODEL (Starting January 1, 2020)

	Year of Proposed Model					
	2020	2021	2022	2023	2024	5-Year Total*
Net Impact To Medicare Program Spending	-40	-50	-50	-60	-60	-260
Changes to Incurred FFS Spending	-30	-40	-40	-40	-50	-200
Changes to MA Capitation Payments	-20	-30	-30	-30	-40	-150
Part B Premium Revenue Offset	10	10	20	20	20	80
Total APM Incentive Payments	0.0	0.0	4.0	4.0	4.0	12.0
Episode Allowed Charges	1,010	1,050	1,080	1,110	1,140	5,390
Episode Medicare Payment	790	820	840	870	890	4,200
Total Number of Episodes	70,000	71,000	73,000	74,000	76,000	364,000
Total Number of Beneficiaries	68,000	69,000	71,000	72,000	74,000	322,000

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

TABLE 16B. PROPOSED ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR PROPOSED RADIATION ONCOLOGY MODEL (Starting April 1, 2020)

	Year of Proposed Model					
	2020	2021	2022	2023	2024	5-Year Total*
Net Impact To Medicare Program Spending	-30	-50	-50	-60	-60	-250
Changes to Incurred FFS Spending	-20	-40	-40	-40	-50	-190
Changes to MA Capitation Payments	-20	-30	-30	-30	-40	-140
Part B Premium Revenue Offset	10	10	20	20	20	80
Total APM Incentive Payments	0.0	0.0	4.0	4.0	4.0	12.0
Episode Allowed Charges	760	1,050	1,080	1,110	1,140	5,130
Episode Medicare Payment	590	820	840	870	890	4,000
Total Number of Episodes	52,000	71,000	73,000	74,000	76,000	346,000
Total Number of Beneficiaries	51,000	69,000	71,000	72,000	74,000	307,000

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

A key assumption underlying the above impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the period used for rate setting and when payments are made. If V&I were to decrease by 1.0 percent annually for the bundled services absent the model, then we estimate Medicare would only reduce net outlays by $50 million ($40 million with an April 1 start date) between 2020 and 2024. Similarly if V&I increases by 1.0 percent annually then net outlays would be reduced by $460 million ($450 million with an April 1 start date) for the projection period. Please note that although V&I growth from 2014 through 2017 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ.

b. ESRD Treatment Choices Model

(1) Overview

Under the ESRD Prospective Payment System (PPS) under Medicare Part B, a single per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. Under the Physician Fee Schedule, medical management of an ESRD beneficiary receiving dialysis by a physician or other practitioner is paid through the MCP. The proposed ETC Model would be a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in section IV. of this proposed rule, for ESRD facilities and to the MCP for Managing Clinicians from January 1, 2020 to June 30, 2026.

Under the proposed ETC Model, there would be two payment adjustments designed to increase rates of home dialysis and kidney and kidney-pancreas transplants through financial incentives. The HDPA would be an upward payment adjustment on certain home dialysis and home dialysis-related claims, as described in proposed § 512.340 and § 512.350 for ESRD facilities and § 512.345 and § 512.350 for Managing Clinicians, during the initial 3 years of the ETC Model.

The PPA would be an upward or downward payment adjustment on certain dialysis and dialysis-related claims submitted by ETC participants, as described in proposed § 512.375(a) and § 512.380 for ESRD facilities and § 512.375(b) and § 512.380 for Managing Clinicians, that would apply to claims with claim through dates beginning on July 1, 2021 and increase in magnitude over the duration of the Model. CMS would assess each ETC Participant's home dialysis rate, as described in proposed § 512.365(b), and transplant rate, as described in proposed § 512.365(c), for each Measurement Year. The ETC Participant's home dialysis rate and transplant rate would be risk adjusted and reliability adjusted, as described in proposed § 512.365(d) and proposed § 512.365(e), respectively. The ETC Participant would receive a Modality Performance Score (MPS)

based on the weighted sum of the higher of the ETC Participant's achievement score or improvement score for the home dialysis rate and the higher of the ETC Participant's achievement score or improvement score for the transplant rate, as described in proposed § 512.370(d). In MY 1 and MY 2, the achievement scores would be calculated in relation to a set of benchmarks based on the historical rates of home dialysis and kidney transplants among ESRD facilities and Managing Clinicians located in comparison geographic areas. We intend to increase these benchmarks over time through subsequent notice and comment rulemaking, as discussed in section IV.C.5.d. of this proposed rule. The improvement score would be calculated in relation to a set of benchmarks based on the ETC Participant's own historical performance. The ETC Participant's MPS for a MY would determine the magnitude of its PPA during the corresponding 6-month PPA Period, which would begin 6 months after the end of the MY. An ETC Participant's MPS would be updated on a rolling basis every 6 months.

The ETC Model would not be a total cost of care model. ETC participants would still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments would continue to be paid as they would be in the absence of the model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the model relative to baseline expenditures. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis and transplant claims reported during 2016 and 2017, the most recent years with complete data available. Both datasets and the proposed risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary.

The ESRD facilities and Managing Clinicians datasets were restricted to the following eligibility criteria. Beneficiaries must be residing in the United States, 18 years of age or older, and enrolled in Medicare Part B. Beneficiaries enrolled in Medicare Advantage or other cost or Medicare managed care plans, who have elected hospice, receiving dialysis for acute kidney injury (AKI) only, or with a diagnosis of dementia were excluded. In addition, the HRR was matched to the claim service facility zip code or the rendering physician zip code for ESRD facility and Managing Clinician, respectively.

The ESRD facilities data were aggregated to the CMS Certification Number (CCN) level for beneficiaries on dialysis identified by outpatient claims with Type of Bill 072X to capture all dialysis services furnished at or through ESRD facilities. Beneficiaries receiving home dialysis services were defined as condition codes 74, 75, 76, and 80. Beneficiaries receiving in-center dialysis services were defined using condition codes 71, 72, and 73. For consistency with the proposed exclusion in proposed § 512.385(a), ESRD facilities with less than 132 total attributed beneficiary months during a given MY were excluded.

The Managing Clinicians' data were aggregated to the group TIN, individual TIN, or NPI (in order of availability) level for beneficiaries on home dialysis and were constructed using outpatient claims with CPT® codes 90965 and 90966. Beneficiaries receiving in-center dialysis were defined by outpatient claims with CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962. A low-volume exclusion was applied to Managing Clinicians in the bottom 5 percent in terms of beneficiary-years for which the Managing Clinician billed the MCP during the year.

The transplant data for ESRD facilities and Managing Clinicians were obtained from Medicare inpatient claims with MS–DRGs 008 and 652; and claims with ICD–10 procedure codes 0TY00Z0, 0TY00Z1, 0TY00Z2, 0TY10Z0, 0TY10Z1, and 0TY10Z2.[137] The beneficiary attribution eligibility criteria in proposed § 512.360(b) and low-volume exclusions in proposed § 512.385 were applied to the transplant data in the ESRD facilities and Managing Clinicians datasets. In addition, the transplant data were further restricted by excluding beneficiaries during any months in which they were 75 years of age or older or for any months in which they were in a skilled nursing facility.

The home dialysis score and transplant score for the PPA were calculated using the following methodology for the ESRD facilities and Managing Clinicians. A reliability adjustment was applied to the home dialysis (transplant) rate to account for the small numbers of beneficiaries attributed to individual ETC Participants and to improve comparisons between ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model for purposes of achievement benchmarking and scoring, described in section IV.C.5.d of this proposed rule. Four credibility tiers of total member months (that is, 400, 600, 800, and 1,000) were constructed with corresponding HRR weights of 80, 60, 40, and 20 percent. ETC Participant behavior for each year was simulated by adjusting the ETC Participant's baseline home dialysis (or transplant) rate for a simulated statistical fluctuation and then summing with the assumed increase in home dialysis (or transplant) rate multiplied by a randomly generated improvement scalar. The achievement and improvement scores were assigned by comparing the participant's simulated home dialysis (or transplant) rate for the MY to the percentile distribution of home dialysis (or transplant) rates in the prior year. Last, the MPS was calculated using the maximum of each achievement or improvement score. The home dialysis score constituted two-thirds of the MPS, and the transplant score one-third of the MPS.

The HDPA calculation required a simplified methodology, with home dialysis and home dialysis-related payments adjusted by 3, 2, and 1 percent during the first 3 years of the model.

The Kidney Disease Education (KDE) benefit utilization and cost data were identified by codes G0420 and G0421, to capture face-to-face individual and group training sessions for chronic kidney disease beneficiaries on treatment modalities. The home dialysis training costs for incident beneficiaries on home dialysis for Continuous Ambulatory Peritoneal Dialysis (CAPD) or Continuous Cycler-Assisted Peritoneal Dialysis (CCPD) were defined using CPT® codes 90989 and 90993 for complete and incomplete training sessions, respectively.

Data from calendar year 2017 were used to project baseline expenditures and the traditional FFS payment system billing patterns were assumed to continue under current law.

(3) Medicare Estimate—Assume Rolling Benchmark

Table 17 summarizes the estimated impact of the ETC Model when assuming a rolling benchmark where the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for

[137] SRTR data was not used in this analysis, as it was not available at the time the analysis was conducted. While this omission adds some small amount of uncertainty to the analysis, we do not believe that this lack of data compromises the validity of the analysis, as the number of kidney and kidney-pancreas transplants not identifiable through claims data is very small.

participation in the ETC Model. We estimate the Medicare program would save a net total of 185 million dollars from the PPA and HDPA between January 1, 2020 and June 30, 2026, less 15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be 169 million dollars in savings. In Table 17, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results were generated from an average of 500 simulations under the assumption that benchmarks are rolled forward with a 1.5 year lag. The projections do not include the Part B premium revenue offset because CMS is proposing that the payment adjustments under the ETC Model would not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary Fee-For-Service effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

As anticipated, the expected Medicare program savings were driven by the net effect of the ESRD facility PPA; a reduction in Medicare spending of 220 million dollars over the period from January 1, 2020 through June 30, 2026. In comparison, the net effect of the Managing Clinician PPA was only 8 million dollars in Medicare savings. This estimate was based on an empirical study of historical home dialysis utilization and transplant rates for FFS beneficiaries that CMS virtually assigned to dialysis facilities and to nephrology practices based on the plurality of associated spending at the beneficiary level. We analyzed the base variation in those facility/practice level measures and simulated the effect of the proposed payment policy assuming providers respond by marginally increasing their share of patients utilizing home dialysis. Random variables were used to vary the effectiveness that individual providers might show in such progression over time and to simulate the level of year-to-year variation already noted in the base multi-year data that was analyzed. The uncertainty in the projection was illustrated through an alternate scenario assuming that the benchmarks against which participants are measured were to not be updated as well as a discussion of the 10th and 90th percentiles of the actuarial model output. These sensitivity analyses are described in sections VII.C.2.b.(3)(a) and VII.C.2.b.(3)(b), respectively. KDE on treatment modalities and home dialysis (HD) training for incident dialysis beneficiaries are relatively small outlays and were projected to represent only relatively modest increases in Medicare spending each year.

The key assumptions underlying the impact estimate are that each ESRD facility or Managing Clinician's share of total maintenance dialysis provided in the home setting was assumed to grow by up to an assumed maximum growth averaging 3 percentage points per year. Factors underlying this assumption about the home dialysis growth rate include; known limitations that may prevent patients from being able to dialyze at home, such as certain common disease types that make peritoneal dialysis impractical (for example, obesity); current equipment and staffing constraints; and the likelihood that a patient new to maintenance dialysis starts dialysis at home compared to the likelihood that a current dialysis patient who dialyzes in center switches to dialysis at home. The 3 percentage point per year max growth rate would in effect move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (for example. Bend, Oregon HRR at about 25 percent), which we believe is a reasonable upper bound on growth over the duration of the ETC Model for the purposes of this actuarial model.

Individual ESRD facilities or Managing Clinicians were assumed to achieve anywhere from zero to 100 percent of such maximum growth in any given year. Thus, the average projected growth for the share of maintenance dialysis provided in the home was 1.5 percentage points per year. Projected forward, this would result in home dialysis ultimately representing approximately 19 percent of overall maintenance dialysis in selected geographic areas by 2026. In contrast, we do not include an official assumption that the overall number of kidney transplants will increase and provide justification for this assumption in the section VII.C.2.b.(4). of the proposed rule. However, as part of the sensitivity analysis for the savings calculations for the model, we lay out different savings scenarios if the incentives ETC Model were to cause an increase in living donation and if the learning system described in section IV.C.12 of this proposed rule were to be successful in decreasing the discard rate of deceased donor kidneys and increasing the utilization rate of deceased donor kidneys that have been retrieved.

TABLE 17. PROPOSED ESTIMATES OF MEDICARE PROGRAM SAVINGS (ROUNDED $M) FOR PROPOSED ESRD TREATMENT CHOICES MODEL

	Year of Proposed Model							
	2020	2021	2022	2023	2024	2025	2026	6.5 Year Total*
Net Impact to Medicare Spending	20	1	-22	-36	-49	-57	-26	**-169**
Overall PPA Net & HDPA	19	-1	-24	-38	-52	-60	-29	**-185**
Clinician PPA Downward Adjustment		-2	-6	-7	-8	-10	-6	-38
Clinician PPA Upward Adjustment		2	5	6	6	8	4	31
Clinician PPA Net		-1	-1	-1	-2	-2	-1	-8
Clinician HDPA	2	1	1					4
Facility Downward Adjustment		-34	-76	-93	-114	-137	-73	-528
Facility Upward Adjustment		18	45	56	64	80	45	307
Facility PPA Net		-15	-32	-38	-51	-57	-28	-220
Facility HDPA	17	14	8					39
Total PPA Downward Adjustment		-36	-82	-100	-122	-147	-79	-566
Total PPA Upward Adjustment		20	49	61	70	87	49	338
Total PPA Net		-16	-32	-38	-52	-60	-29	-228
Total HDPA	19	15	9					43
KDE Benefit Costs	0	1	1	1	1	1	1	**5**
HD Training Costs	1	1	1	1	2	2	2	**10**

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending.

(a) Sensitivity Analysis: Medicare Estimate—Assume Fixed Benchmark

An alternative model specification was analyzed where benchmarks remain *fixed* at baseline year 0 over time (results available upon request). Both the fixed and rolling benchmark assumptions projected about 19 million dollars in increased overall HDPA Medicare payments to ESRD facilities and Managing Clinicians in 2020. We project about 1 million dollars in additional HD training add-on payments. This would represent about 20 million dollars in increased Medicare expenditures in 2020 overall. Both specifications of the benchmark also projected the net impact of approximately 1 million dollars in increased Medicare expenditures in 2021.

The two scenarios diverge after 2021, with large differences observed in overall net PPA and HDPA savings/losses. Table 17 illustrates that when benchmarks are rolled forward, using the methodology described in section VII.C.2.b.(3), the overall *savings* in PPA net and HDPA increase each year during the 2022–2026 period. In contrast, when benchmark targets are fixed, in 2022 the overall PPA net and HDPA savings increase to 16 million dollars, followed by overall *losses* in years 2022–2026 of 0, 35, 89, and 62 million dollars, respectively. The fixed benchmark would allow the ESRD facilities and Managing Clinicians to have more favorable achievement and improvement scores over time compared to the rolling benchmark method. In summary, the total of overall net PPA and HDPA from January 1, 2020 through June 30, 2026, with the fixed benchmark, was 189 million dollars in losses, compared to a total of 185 million dollars in savings with the rolling benchmark method. The net impact on Medicare spending for the PPA and HDPA using the fixed benchmark method is 203 million dollars in *losses.*

(b) Sensitivity Analysis: Medicare Savings Estimate—Results for the 10th and 90th Percentiles

Returning to the methodology used for the Medicare estimate with a rolling benchmark, we compare the results (available upon request) for the top 10th and 90th percentiles of the 500 individual simulations to the average of all simulation results reported in Table 17. Since the impact on Medicare spending for the proposed ETC Model using the rolling benchmark method is estimated to be in savings rather than losses, the top 10th and 90th percentiles represent the most optimistic and conservative projections, respectively. The overall net PPA and HDPA for the top 10th and 90th percentiles using the rolling benchmark method are 264 and 112 million dollars in savings (compared to 185 million dollars in savings in Table 17).

(4) Effects on Kidney Transplantation

Kidney transplantation is considered the optimal treatment for most ESRD beneficiaries. However, while the proposed PPA includes a one-third weight on the ESRD facilities' or Managing Clinician's kidney transplant rate, we decided to be conservative and did not include an assumption that the overall number of kidney transplants will increase. The number of ESRD patients on the kidney transplant wait list has for many years far exceeded the annual number of transplants performed. Transplantation rates have not increased to meet such demand because of the limited supply of donated kidneys. The United States Renal Data System [138] reported 20,161 kidney transplants in 2016 compared to an ESRD transplant waiting list of over 80,000. Living donor kidney

[138] United States Renal Data System. 2018. ''ADR Reference Table E6 Renal Transplants by Donor Type.''

transplantation (LDKT) has actually declined in frequency over the last decade while deceased donor kidney transplantation (DDKT) now represent nearly three out of four transplants as of 2016.

The PPA's transplant incentive would likely increase the share of ESRD Beneficiaries who join the transplant wait list but is unlikely to impact the donation supply limitation. There is evidence that the overall quantity of transplants could be positively impacted by reducing the discard rate for certain DDKT with lower quality, high-Kidney Donor Profile Index (KDPI) organs. However, while such transplantation has been shown to improve the quality of outcomes for patients, kidney transplant centers have reported barriers to their use including a higher cost of providing care in such relatively complex transplant cases relative to Medicare's standard payment. Because the PPA would not impact payment to transplant centers the ETC Model would not mitigate the barrier to increased marginal kidney transplantations. Furthermore, even to the extent that marginal DDKT were somehow improved because of PPA incentives, evidence also suggests that the impact of DDKT with high-KDPI organs may not reduce overall spending despite improving the quality of outcomes for patients.

It is possible that the ETC Model could generate additional live kidney donations for which significant Medicare program savings could be realized. For example, additional patient education could lead more beneficiaries to find donors by tapping into resources already available to remove financial disincentives to donors (for example, payment for travel, housing, loss of wages, and post-operative care).[139] [140] The ETC Model as proposed does not include a proposal to assist with minimizing disincentives to living donors for their kidney donation; however, qualified donors may apply for financial assistance through the National Living Donor Assistance Center (NLDAC), which administers federal funding received from HRSA under the federal Organ Donation Recovery and Improvement Act.[141] All applicants under this Act are means tested, with preference given to recipients and donors who are both below 300 percent of the federal poverty line (FPL). Approved applicants can receive up to $6,000 to cover travel, lodging, meals, and incidental expenses. In 2017, only 8.38 percent of the approximate 6,000 total living kidney donations [142] received NLDAC support, resulting in up to $3 million in paid expenses per year. Additional methods are necessary to decrease financial disincentives for kidney donors and their recipients who exceed the means testing criteria of the NLDAC.

The costs/savings incurred by kidney transplantation vary by donor type. Axelrod et al. (2018) used Medicare claims data with Medicare as the primary payer linked to national registry and hospital cost-accounting data provides evidence for the cost-savings of kidney transplantations by donor type compared to dialysis.[143] The authors estimated ESRD expenditures to be $292,117 over 10 years per beneficiary on dialysis. LDKT was cost-saving at 10 years, reducing expected expenditures for ESRD treatment by 13 percent ($259,119) compared to maintenance dialysis. In contrast, DDKT with low-KDPI organs was cost-equivalent at $297,286 over 10 years compared to dialysis. Last, DDKT with high-KDPI organs resulted in increased spending of $330,576 over 10 years compared to dialysis.

The approximately $33,000 in savings per beneficiary over 10 years for LDKT compared to maintenance dialysis is likely a lower bound since living donation would help reduce the number of beneficiaries under the age of 65 who would be eligible for Medicare enrollment. The lower bound conditional savings can be adjusted to account for additional savings through reduced Medicare enrollment by considering the share of potential new live donations across three main scenarios.

The LDKT expected cost of $259,119 over 10 years per beneficiary projected by Axelrod et al. (2018) assumes Medicare primary payer status. For roughly 25 percent of LDKTs, Medicare can be assumed to be the primary payer regardless of transplant success; therefore, the projected spending need not be adjusted. For the next 25 percent of LDKTs, we assumed the beneficiary is on dialysis and Medicare is the primary payer, but they would eventually leave Medicare enrollment if they had a transplant. We adjusted the expected Medicare spending for these cases downward by 33 percent. This projected a savings of approximately $119,000 over 10 years relative to the baseline spending projection of $292,117 over 10 years for beneficiaries on dialysis. The third scenario—covering the remaining 50 percent of LDKTs—assumes Medicare is not the primary payer when the transplant occurs. In this case, we assumed that Medicare spending is nominal relative to baseline spending and we adjust downward by 33 percent (that is, the beneficiary would take up to 30 months to become a Medicare primary payer enrollee absent the transplant), which projected a savings of approximately $195,000 over 10 years. The projected weighted average program savings for LDKT is $136,000 over 10 years per beneficiary.

Therefore, a 20 percent increase in the rate of LDKT in model markets in a single year, representing about 500 new transplants mainly from relatives of recipients, would produce approximately $68 million in program savings over 10 years (and multiples thereof for each successive year the living donor transplant rate were thusly elevated).

The model also includes an investment in learning and diffusion for improving the utilization of deceased donor kidneys that are currently discarded at a rate of approximately 19 percent nationally.[144] Similar to the estimate above on the average impact to Medicare spending for LDKT, we estimated an average marginal savings to Medicare for DDKT by adjusting costs reported by Axelrod et al. (2018) for DDKT with high-KDPI to account for effects on Medicare payer status. We include three scenarios based on type of payer.

First, we assumed 50 percent of newly harvested deceased-donor kidneys would be for beneficiaries enrolled in Medicare, regardless of ESRD status. This scenario aligns with the Medicare primary payer estimates from the study, approximately $38,000 higher spending for DDKT with high-KDPI over 10 years relative to maintenance dialysis. Second, we assumed 30 percent of marginal DDKT would be for

[139] Salomon DR, Langnas AN, Reed AI, et al. 2015. ''AST/ASTS Workshop on Increasing Organ Donation in the United States: Creating an 'Arc of Change' From Removing Disincentives to Testing Incentives.'' *American Journal of Transplantation* 15: 1173–1179.

[140] Tong A, Chapman JR, Wong G, Craig JC. 2014. ''Perspectives of Transplant Physicians and Surgeons on Reimbursement, Compensation, and Incentives for Living Kidney Donors.'' *American Journal of Kidney Disorders* 64(4): 622–632.

[141] Public Law 108–216 (section 377 of the Public Health Service (PHS) Act, 42 U.S.C. 274f).

[142] OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. *https://www.srtr.org/reports-tools/srtroptn-annual-data-report/.*

[143] Axelrod DA, Schnitzler MA, Xiao H, *et al.* 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176.

[144] OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. *https://www.srtr.org/reports-tools/srtroptn-annual-data-report/.*

beneficiaries with Medicare as their primary coverage where the transplant spending was adjusted downward by 33 percent to account for reduced liability for patients returning to non-Medicare status. Third, we assumed 20 percent of DDKT with high-KDPI would involve beneficiaries not yet under Medicare as their primary payer. For this scenario, we adjusted the baseline dialysis spending downward by 33 percent to account for initial non-Medicare status during the waiting period and for the transplant spending we assumed 25 percent of baseline Medicare spending would still be present due to early graft failure before the end of the 10-year window (recognizing the shorter lifespan high-KDPI organs tend to offer recipients).

Combining these assumptions produced an average 10 year savings to Medicare of approximately $32,000 per beneficiary for DDKT with high-KDPI. Overall, we found an increase in marginal kidney utilization such that the national discard rate would drop to 15 percent by the end of the model testing period, representing approximately 2,360 additional transplants and an estimated $76 million in federal savings.

For both living and deceased donor transplants, the illustrated potential effect of the model would reduce long run program spending by $143 million. Costs for this effort include a learning and diffusion investment of $25 million over the model testing period and a potential increase in PPA adjustments to clinician and facility payments of approximately $30 million. The projected increase in transplantation is estimated to produce a net savings of $88 million—a net return on investment of approximately 1.6.

(5) Effects on the KDE Benefit and HD Training Add-Ons

The KDE benefit has historically experienced very low uptake, with less than 2 percent of eligible Medicare beneficiaries utilizing this option. A recent report summarized barriers to adequate education on home dialysis.[145] Kidney disease education may: Not be provided at all, be done only once, not be appropriate for patient's literacy level or not provided in patient's native language, not be done until after patient starts in-center hemodialysis, and/or not be provided to caregivers.

The proposed ETC Model would incorporate waivers of select KDE benefit requirements that should make these educational sessions on treatment modality options more accessible to beneficiaries targeted by the model and address some of the barriers previously described. We assume the KDE benefit utilization growth rate to increase from 2.2 in 2020 to 3.2 in 2026. To arrive at this assumption, we began with the current low utilization of the benefit. The utilization rate of the KDE benefit during the first year of the Model (2020) was set to 2 percent, which is consistent with the current rate of utilization of the benefit. We set the utilization growth rate to increase by 0.2 percentage points each year during 2021 to 2026. Although the ETC Model will allow different types of health care providers to furnish the KDE benefit to beneficiaries, there is no direct evidence that this will cause an increase in the utilization growth rate that differs significantly from the historical rate. Challenges to increasing the utilization growth rate include: The beneficiary's Managing Clinician may not inform the beneficiary of the option to seek KDE benefit sessions for a variety of reasons (for example.—the Managing Clinician is unaware of the KDE benefit, alternative treatment modalities are not feasible for the beneficiary, or the clinician believes that the beneficiary would not be able to make an informed choice about dialysis modality after receiving the KDE benefit); if informed of the KDE benefit option, the beneficiary may prefer to rely on their Managing Clinician's recommendation rather than receive education about their treatment options; and the beneficiary may not want to have an additional one to six sessions with a health care provider for the provision of the KDE benefit, as beneficiaries with late stage CKD and ESRD are medically fragile and already in frequent contact with the health care system. This results in a projected doubling of the costs attributed to the KDE benefit to approximately one million dollars in 2026.

The impacts of increased utilization of the home dialysis (HD) training add-on payment adjustment under the ESRD PPS are expected to be larger than the KDE benefit costs as these trainings will be required for all incident beneficiaries on home dialysis. Assuming a stable 3 percent growth rate in home dialysis per year, the 7 year total in HD training costs is projected to be 10 million dollars.

3. Effects on Medicare Beneficiaries

a. Radiation Oncology Model

We anticipate that the RO Model would benefit or have a negligible impact on the cost to beneficiaries receiving RT services. Under current policy, Medicare FFS beneficiaries are generally required to pay 20 percent of the allowed charge for services furnished by HOPDs and physicians (for example, those services paid for under the OPPS and MPFS, respectively). This policy would remain the same under the RO Model. More specifically, beneficiaries would be responsible for 20 percent of each of the PC and TC episode payments made under the RO Model. Since we are proposing to take a percentage ''discount'' off of the total payment to participants for both PC and TC episode payment amounts (this discount representing savings to Medicare), the total allowed charge for services furnished by HOPDs and physicians would decrease. Thus, beneficiary cost-sharing, on average, would be reduced relative to what typically would be paid under traditional Medicare FFS for an episode of care. In addition, the limit on beneficiary cost-sharing in the HOPD setting to the inpatient deductible would continue under the RO Model.

In addition, we note that, because episode payment amounts under the RO Model would include payments for RT services that would likely be provided over multiple visits, individual beneficiary coinsurance payments would likewise be higher than they would otherwise be for an individual RT service visit. We would encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments.

b. ESRD Treatment Choices Model

We anticipate that the ETC Model would have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy would remain the same under the ETC Model. However, the Model would apply the Clinician PPA and the Clinician HDPA to the amount otherwise paid by Part B to ensure beneficiaries are held harmless from any effect on cost sharing. Additionally, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for Part B ESRD PPS services furnished by an ESRD facility. This policy would remain the same under the ETC Model. However, CMS proposes to waive

[145] Chan CT, Wallace E, Golper TA, *et al.* 2018. ''Exploring Barriers and Potential Solutions in Home Dialysis: An NKF–KDOQI Conference Outcomes Report.'' *American Journal of Kidney Disease* 73(3): 363–371.

certain requirements of title XVIII of the Act as necessary to test the Facility PPA and Facility HDPA proposed under the Model and proposes that beneficiaries would be held harmless from any effect of these payment adjustments on cost sharing.

In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis as opposed to in-center dialysis. Studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; [146] as well as better overall, physical, and psychological health [147] [148] in comparison to other dialysis options.

4. Effects on RO and ETC Participants

RO participants will be given instructions on how to bill for patients, using RO Model-specific HCPCS codes. We expect it would take medical coding staff approximately 0.72 hours [(((~36 pages * 300 words/per page)/250 words per minute)/60 minutes) = 0.72] [149] to read and learn the payment methodology and billing sections of the rule. In addition, we would add one hour to review the relevant MLN Matters publication, 1 hour to read the RO Model billing guide, and one hour to attend the billing guidance webinar, for a total of 3.72 hours. We estimate the median salary of a Medical Records and Health Information Technician is $19.40 per hour, at 100 percent fringe benefit for a total of $38.80, using the wage information from the BLS.[150] The total cost of learning the billing system for the RO Model thus is $144.34 per participant, or approximately $167,000 in total (1,157 expected participants × $144.34/participant = $167,000 total).

The ETC Model would not alter the way ETC Participants bill Medicare. Therefore, we believe that there would be no additional burden for ETC Participants related to billing practices.

We believe the burden for audits and record retention do not diverge from existing provider requirements in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (HIPAA) administrative simplification rules (45 CFR 164.316(b)(2)), which require a covered entity, such as a physician billing Medicare, to retain required documentation for six years from the date of its creation or the date when it last was in effect, whichever is later. While the HIPAA Privacy Rule does not include medical record retention requirements, it does require that covered entities apply appropriate administrative, technical, and physical safeguards to protect the privacy of medical records and other protected health information (PHI) for whatever period such information is maintained by a covered entity, including through disposal. The Privacy Rule is available at 45 CFR 164.530(c). In addition, CMS requires records of providers submitting cost reports to be retained in their original or legally reproduced form for a period of at least 5 years after the closure of the cost report. This requirement is available at 42 CFR 482.24(b)(1). Given these existing requirements, we do not believe that the audit or record retention requirement in the RO Model or the ETC Model will create an additional burden or impact on participants.

Similarly, monitoring and compliance requirements for the RO Model and the ETC Model would not diverge from general monitoring requirements for Medicare Part B providers. We believe that the requirements in this section do not add additional burden or impose regulatory impact on participants.

The model evaluation for both the RO Model and the ETC Model would likely include beneficiaries and providers completing surveys. Burden for these surveys will depend on the length, complexity, and frequency of surveys administered as needed to ensure confidence in the survey findings. We would make an effort to minimize the length, complexity, and frequency of the surveys. A typical survey on average would require about 20 minutes of the respondent's time. In other evaluations of models where a survey is required, the frequency of surveys varies from a minimum of one round of surveys to annual surveys.

We believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses in Section VII.C.5.a would also apply to RO Model participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which we estimate to be approximately $388.00 per entity per year. Since we estimate approximately 1,157 RO Model participants, then total burden estimate for collecting and reporting quality measures and clinical data would be approximately $449,000. Additionally, the ETC Model does not require any additional quality measure or clinical data element reporting by ETC Participants. Therefore, we believe that there is no additional burden for ETC Participants related to quality measures or clinical data reporting.

Finally, we believe the burden estimate for reading and interpreting this proposed rule that is provided for Small Businesses would also apply to RO Model participants and ETC participants that are not considered small entities. The burden estimate for reading and interpreting this proposed rule may be equal to or less than that for small businesses. We estimated that cost of reading the rule for RO participants would be approximately $466.89 per entity with a total cost of approximately $1,354,000 (2,900 eligible entities × $466.89/participant). In sum, we estimate that reading the RO Model rule, learning the RO billing system, and submitting quality measures and clinical data to the RO Model would cost approximately $1,000 per RO participant, and collectively cost approximately $1,156,000 across the 1,157 RO participants, and an additional $814,000 for those RO providers who read the rule, but are not ultimately selected as RO participants, for a total cost $1,970,000. Similarly, we base our estimate for the cost of reading the proposed rule for ETC participants on the same cost per participant as used for the RO Model, that is, $466.89 per entity. We assume that all ESRD facilities and managing clinicians will read the rule, even though only a subset of each category would participate in the Model. Therefore, the collective cost will be $6,714,000 (14,380 entities reading the rule (7,097 ESRD facilities plus 7,283 Managing Clinicians) times $466.89).

5. Regulatory Flexibility Act (RFA)

The RFA, as amended, requires agencies to analyze options for

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[146] Dąbrowska-Bender M, Dykowska G, Zuk W, et al. 2018. ''The impact on quality of life of dialysis patients with renal insufficiency.'' *Patient Prefer Adherence* 12: 577–583.

[147] Makkar V, Kumar M, Mahajan R, Khaira NS. 2015. ''Comparison of Outcomes and Quality of Life between Hemodialysis and Peritoneal Dialysis Patients in Indian ESRD Population.'' *J Clin Diagn Res.* 9(3): OC28–OC31

[148] Van Eps CL, Jeffries JK, Johnson DW, et al. 2010. ''Quality of life and alternate nightly nocturnal home hemodialysis.'' *Hemodial Int.*14(1):29–38.

[149] *https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.*

[150] For the RO Model, we use the estimated median hourly wage of $19.40 per hour, plus 100 percent overhead and fringe benefits. Estimating the hourly wage is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs. *https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm.*

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. As discussed in sections VII.5.a and VII.5.b, the Secretary has considered small entities and has determined and certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

a. Radiation Oncology Model

This proposed rule affects: (1) Radiation oncology PGPs that furnish RT services in both freestanding radiation therapy centers and HOPDs; (2) PGPs that furnish RT services only in HOPDs; (3) PGPs that are categorized as freestanding radiation therapy centers; and (4) HOPDs. The majority of HOPDs and other RT providers and RT suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (defined as having minimum revenues of less than $11 million to $38.5 million in any 1 year, depending on the type of provider; the $38.5 million per year threshold is for hospitals, whereas the $11 million per year threshold is for other entities). (*https://www.sba.gov/document/support--table-size-standards*). States and individuals are not included in the definition of small entity.

HHS uses an RFA threshold of at least a 5 percent impact on revenues of small entities to determine whether a proposed rule is likely to have ''significant'' impacts on small entities.[151] Throughout the rule we describe how the proposed changes to a prospective episode payment may affect PGPs and HOPDs.

The RO Model would include only Medicare FFS beneficiaries receiving RT services by selected PGPs (including freestanding radiation therapy centers) and HOPDs. During 2018, 39 percent of Medicare beneficiaries with both Part A and B coverage on average are estimated to have enrolled in Medicare Advantage plans.[152] PGPs and HOPDs also serve patients with other coverage, for example, through Medicare or commercial insurance. We believe that on average, Medicare FFS payments to PGPs would be reduced by 5.9 percent and Medicare FFS payments to HOPDs would be reduced by 4.2 percent and would not change with an April 1 start date. Given that this model is limited to only Medicare FFS beneficiaries, not other payers including Medicare Advantage and commercial insurance, which combined we expect to be about 50 to 60 percent of total HOPD and PGP revenue for RT services, we expect that the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. Therefore, we have determined that this proposed rule would not have a greater than 5 percent impact on total revenues on a substantial number of small entities. We estimate the administrative costs of adjusting to and complying with the quality measure and clinical data element reporting requirements proposed in the RO Model for small entities to be approximately $388.00 per entity per year. To estimate the costs per small entity, we assume that a Medical Records & Health Information Technician with an Hourly salary (from BLS) plus 100 percent fringe benefits would cost $38.80/hour[153] and would report the information on quality measures and clinical data elements. We would expect submission of the 4 quality data measures to take approximately 8 hours and would require submission once a year, ($38.80 × 8.0 hours × 1 submission) = $310.40. We would expect the submission of clinical data elements to take up to an hour, but occur twice a year, that is. ($38.80 × 1 hour × 2 submission) = $77.60. The burden costs per small entity associated with measure and data reporting proposals should be small because three of the four measures proposed for the RO Model are already in use in other CMS programs; and compliance with the Treatment Summary Communication (the measure not currently in use) is a best practice that should already be the standard of care across PGPs and HOPDs.

We further estimate the administrative cost of reading and interpreting this proposed rule per small entity at approximately $446.89. We expect that a medical health service manager reading 250 per minutes could review the rule in approximately 4.66 hours [(approximately 233 pages * 300 words/per page)/250 words per minute)[154]/60 minutes)]. We estimate the salary of a medical and health service manager is $95.90 per hour, using the wage information from the BLS including overhead and fringe benefits.[155] Assuming an average reading speed for pages relevant to the RO Model, we estimate that it would take approximately 4.66 hours for the staff to review half of this proposed rule. For each provider that reviews the rule, the estimated cost based on the expected time and salary of the person reviewing the rule ($446.89 = ($95.90 * 4.66 hrs).

We welcome public comments on our estimates and analysis of the impact of the proposed rule on those small entities.

b. ESRD Treatment Choices Model

The proposed rule includes as model participants: (1) Managing Clinicians; and (2) ESRD facilities. We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians would be small entities and that the greater majority of ESRD facilities would not be small entities. Throughout the rule we describe how the proposed adjustments to certain payments for dialysis-related services furnished to ESRD beneficiaries may affect Managing Clinicians and ESRD facilities participating in the ETC Model. The great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business (having minimum revenues of less than $11 million to $38.5 million in any 1 year, varying by type of provider and highest for hospitals) with a minimum threshold for small business size of $38.5 million (*https://www.sba.gov/document/support--table-size-standardshttp://www.sba.gov/content/small-businesssize-standards*). The great majority of ESRD facilities are not small entities as they are owned in whole or in part of entities that do not meet the SBA definition of small entities.

The HDPA in the ETC Model would be a positive adjustment on payments for specified home dialysis and home dialysis-related services. The proposed PPA in the ETC Model, which includes both positive and negative adjustments on payments for dialysis services, would exclude ESRD facilities with fewer than 132 attributed beneficiary-months during the relevant year and the Managing Clinicians with the lowest volume of claims for the MCP using a percentile based exclusion threshold.

For the remaining small entities that are above the exclusion threshold and randomly selected for participation, the

[151] Office of Advocacy, Small Business Administration. (2012). *A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272,* Retrieved from *www.sba.gov/sites/default/files/rfaguide_0512_0.pdf* (accessed March 18, 2019).

[152] This figure comes from the 2018 Medicare Trustees Report, Table IV.V1, p151 from the footnote that has the A and B share.

[153] *https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm.*

[154] *https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.*

[155] For the RO Model, we use an estimated median hourly wage of $47.95 per hour, plus 100 percent overhead and fringe benefits. *https://www.bls.gov/oes/current/oes119111.htm.*

design of the ETC Model would incorporate a risk adjustment and a reliability adjustment to allow for the calculation of home dialysis rates and transplant rates for both small entities and larger entities that may be owned in whole or in part by another company.

The risk adjustment would account for the underlying variation in the patient population of individual ESRD facilities and Managing Clinicians. The risk adjustment for the home dialysis rate would be based on the most recent final risk score for the beneficiary, calculated using the CMS–HCC (Hierarchical Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program, as described in section IV.C.5.b.(3) of the proposed rule. The transplant rate is proposed to be risk adjusted by age, as described in section IV.C.5.b.(3) of the proposed rule.

The reliability adjustment would create a weighted average between the individual ETC Participant's home dialysis rate and transplant rate and the aggregate home dialysis rate and transplant rate of the ETC Participants aggregation group, with the relative weights of the two components based on the statistical reliability of the individual ETC Participant's home dialysis rate and transplant rate. The reliability adjustment allows for comparable performance rates for ESRD facilities and Managing Clinicians across the size spectrum.

Taken together, the proposed low volume threshold exclusions, risk adjustments, and reliability adjustments previously described, with the fact that the ETC Model would affect Medicare payment only for select services furnished to Medicare FFS beneficiaries, we have determined that this proposed rule would not have a greater than 5 percent impact on a substantial number of small entities.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that the proposed RO Model and ETC Model would not have a significant impact on the operations of a substantial number of small rural hospitals.

6. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that is approximately $154 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

7. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications.

This rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication because both the RO Model and ETC Model are Federal payment programs impacting Federal payments only and do not implicate local governments or state law. Therefore, the requirements of Executive Order 13132 are not applicable.

D. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule, if finalized as proposed, is not expected to be subject to the requirements of E.O. 13771 because it is estimated to result in no more than *de minimis* costs.

E. Alternatives Considered

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and the rationale for each of the proposed policies. We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these.

This proposed rule contains a proposed model specific to radiation oncology. It provides descriptions of the requirements that we propose to waive, identifies the proposed payment methodology to be tested, and presents rationales for our decisions and, where relevant, alternatives that were considered. We carefully considered the alternatives to this proposed rule, including whether the RO Model should be implemented by all RT providers and RT suppliers nationwide. We concluded that it would be best to test the model using a subset of all RT providers and RT suppliers in order to compare them to the RT providers and RT suppliers that would not be participating in the RO Model.

This proposed rule also contains a proposed model specific to ESRD. It provides descriptions of the requirements that we propose to waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our decisions, and where relevant, alternatives that were considered. We carefully considered the alternatives to this proposed rule, including whether the model should be implemented to include more or fewer ESRD facilities and Managing Clinicians. We concluded that it would be best to test the model with approximately half of ESRD facilities and Managing Clinicians in the U.S. in order to have an effective comparison group and to provide the best opportunity for an accurate and thorough evaluation of the model's effects.

We welcome comments on our proposals and the alternatives we have identified.

F. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a4*) in Tables 18 and 19, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis.

TABLE 18: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR THE RADIATION ONCOLOGY MODEL

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$48 million (-$46 million with an April 1 start date)	2018	7%	2020 – 2024
	-$50 million (-$48 million with an April 1 start date)	2018	3%	2020 – 2024
From Whom to Whom	From the federal government to healthcare providers			

TABLE 19: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR END STAGE RENAL DISEASE (ESRD) TREATMENT CHOICES MODEL

Category	Assuming no change in the rate of patients receiving services	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$20 million	Table 17
Annualized monetized transfers: Discount rate 3%	$22 million	Table 17
From whom to whom?	From the Federal Government to ESRD facilities and Managing Clinicians	

G. Conclusion

This analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this proposed rule, we estimate that the financial impact of the Radiation Oncology Model and ESRD Treatment Choices Model proposed here would be net federal savings of $429 million ($419 million with an April 1 start date) over a 5 year performance period (2020 through 2024).

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble and under the authority at 42 U.S.C. 1302, 1315(a), and 1395hh, the Centers for Medicare & Medicaid Services proposed to amend 42 CFR chapter IV by adding part 512 to read as follows:

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

Subpart A—General Provisions Related to Innovation Center Models

Sec.

Subpart B—Radiation Oncology Model

General

RO Model Participation

Scope of Episodes Being Tested

Pricing Methodology

Billing and Payment

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Medicare Program Waivers

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Subpart C—ESRD Treatment Choices Model

General

ESRD Treatment Choices Model Scope and Participants

Home Dialysis Payment Adjustment

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

Subpart A—General Provisions Related to Innovation Center Models

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements certain general provisions for the Radiation Oncology Model implemented under subpart B (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C (ETC Model), collectively referred to in this subpart as Innovation Center models. Except as specifically noted in this part, the regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare Fee-For-Service (FFS), including provisions regarding payment, coverage, or program integrity.

(b) *Scope.* The regulations in this subpart apply to model participants in the RO Model (except as otherwise noted in § 512.160(b)(6)) and to model participants in the ETC Model. This subpart sets forth the following:

(1) Basis and scope.

(2) Beneficiary protections.

(3) Model participant requirements for participation in model evaluation and monitoring, and record retention.

(4) Rights in data and intellectual property.

(5) Monitoring and compliance.

(6) Remedial action and termination by CMS.

(7) Limitations on review.

(8) Miscellaneous provisions on bankruptcy and notification.

§ 512.110 Definitions.

For purposes of this part, the following terms are defined as follows unless otherwise stated:

Beneficiary means an individual who is enrolled in Medicare FFS.

Change in control means any of the following:

(1) The acquisition by any ''person'' (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities;

(2) The acquisition of the model participant by any individual or entity;

(3) The sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant; or

(4) The approval and completion of a plan of liquidation of the model participant, or an agreement for the sale or liquidation of the model participant.

Covered services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Days means calendar days.

Descriptive model materials and activities means general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. The following communications are not descriptive model materials and activities: Communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of ''marketing'' as that term is defined at 45 CFR 164.501.

Downstream participant means an individual or entity that has entered into a written arrangement with a model participant pursuant to which the downstream participant engages in one or more Innovation Center model activities.

Innovation Center model means the RO Model implemented under subpart B or the ETC Model implemented under subpart C.

Innovation Center model activities means any activities impacting the care of model beneficiaries related to the test of the Innovation Center model under the terms of this part.

Medically necessary means reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

Model beneficiary means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of this part.

Model participant means an individual or entity that is identified as a participant in the Innovation Center model under the terms of this part.

Model-specific payment means a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers.

Provider means a ''provider of services'' defined under section 1861(u) of the Act and codified in the definition of ''provider'' at § 400.202 of this chapter.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

US Territories means American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

§ 512.120 Beneficiary protections.

(a) *Beneficiary freedom of choice.* (1) The model participant and its downstream model participants must not restrict beneficiaries' ability to choose to receive care from any provider or supplier.

(2) The model participant and its downstream model participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. Notwithstanding the foregoing, the model participant and its downstream model participants may communicate to model beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of this part and applicable law.

(b) *Availability of services.* (1) The model participant and its downstream participants must continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law. Model beneficiaries and their assignees retain their rights to appeal claims in

accordance with part 405, subpart I of this chapter.

(2) The model participant and its downstream participants must not take any action to select or avoid treating certain Medicare beneficiaries based on their income levels or based on factors that would render the beneficiary an ''at-risk beneficiary'' as defined at § 425.20 of this chapter.

(3) The model participant and its downstream participants must not take any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as ''cherry-picking.''

(c) *Descriptive model materials and activities.* (1) The model participant and its downstream participants must not use or distribute descriptive model materials and activities that are materially inaccurate or misleading.

(2) The model participant and its downstream participants must include the following statement on all descriptive model materials and activities: ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.''

(3) The model participant and its downstream participants must retain copies of all written and electronic descriptive model materials and activities and appropriate records for all other descriptive model materials and activities in a manner consistent with § 512.135(c).

(4) CMS reserves the right to review, or have a designee review, descriptive model materials and activities to determine whether or not the content is materially inaccurate or misleading. This review would take place at a time and in a manner specified by CMS once the descriptive model materials and activities are in use by the model participant.

§ 512.130 Cooperation in model evaluation and monitoring.

The model participant and its downstream participants must comply with the requirements of § 403.1110(b) of this chapter and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under § 512.150, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

§ 512.135 Audits and record retention.

(a) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model.

(b) *Access to records.* The model participant and its downstream participants must maintain and give the Federal Government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the Innovation Center model, including without limitation, documents and other evidence regarding all of the following:

(1) The model participant's and its downstream participants' compliance with the terms of the Innovation Center model, including this subpart.

(2) The accuracy of model-specific payments made under the Innovation Center model.

(3) The model participant's payment of amounts owed to CMS under the Innovation Center model.

(4) Quality measure information and the quality of services performed under the terms of the Innovation Center model, including this subpart.

(5) Utilization of items and services furnished under the Innovation Center model.

(6) The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) *Record retention.* (1) The model participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of six years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, in which case the records must be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2) If CMS notifies the model participant of the special need to retain records pursuant to paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the model participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.

§ 512.140 Rights in data and intellectual property.

(a) CMS may use any data obtained under §§ 512.130, 512.135, and 512.150 to evaluate and monitor the Innovation Center model and may disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. Data to be disseminated may include patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources.

(b) Notwithstanding any other provision of this part, all data that has been confirmed by CMS to be proprietary trade secret information and technology of the model participant or its downstream participants will not be released by CMS or its designee(s) without the express written consent of the model participant or its downstream participant, unless such release is required by law.

(c) If the model participant or its downstream participant wishes to protect any proprietary or confidential information that it submits to CMS or its designee, the model participant or its downstream participant must label or otherwise identify the information as proprietary or confidential. Such assertions will be subject to review and confirmation by CMS prior to CMS' acting upon such assertions.

§ 512.150 Monitoring and compliance.

(a) *Compliance with laws.* The model participant and each of its downstream

participants must comply with all applicable laws and regulations.

(b) *CMS monitoring and compliance activities.* (1) CMS may conduct monitoring activities to ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model including this subpart. Such monitoring activities may include, without limitation—

(i) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires;

(ii) Audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants;

(iii) Interviews with members of the staff and leadership of the model participant and its downstream participants;

(iv) Interviews with beneficiaries and their caregivers;

(v) Site visits to the model participant and its downstream participants, performed in a manner consistent with § 512.150(c);

(vi) Monitoring quality outcomes and clinical data, if applicable; and

(vii) Tracking patient complaints and appeals.

(2) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to model beneficiaries.

(c) *Site visits.* (1) In a manner consistent with § 512.130, the model participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the Innovation Center model and the monitoring of the model participant's compliance with the terms of the Innovation Center model, including this subpart.

(2) To the extent practicable, CMS or its designee will provide the model participant or downstream participant with no less than 15 days advance notice of any site visit. To the extent practicable, CMS will attempt to accommodate a request for particular dates in scheduling site visits. However, the model participant or downstream participant may not request a date that is more than 60 days after the date of the initial site visit notice from CMS.

(3) The model participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) Notwithstanding the foregoing, CMS may perform unannounced site visits at the office of the model participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(5) Nothing in this part shall be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Right to correct.* If CMS discovers that it has made or received an incorrect model-specific payment under the terms of the Innovation Center model, CMS may make payment to, or demand payment from, the model participant.

(e) *OIG authority.* Nothing contained in the terms of the Innovation Center Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal Government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants for violations of any statutes, rules, or regulations administered by the Federal Government.

§ 512.160 Remedial action.

(a) *Grounds for remedial action.* CMS may take one or more remedial actions described in paragraph (b) of this section if CMS determines that the model participant or a downstream participant:

(1) Has failed to comply with any of the terms of the Innovation Center Model, including this subpart.

(2) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(3) Has taken any action that threatens the health or safety of a beneficiary or other patient.

(4) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model.

(5) Has undergone a change in control that presents a program integrity risk.

(6) Is subject to any sanctions of an accrediting organization or a Federal, state, or local government agency.

(7) Is subject to investigation or action by HHS (including the HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

(8) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation.

(2) Require the model participant to provide additional information to CMS or its designees.

(3) Subject the model participant to additional monitoring, auditing, or both.

(4) Prohibit the model participant from distributing model-specific payments, as applicable;

(5) Require the model participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the Innovation Center model.

(6) In the ETC Model only, terminate the ETC Participant from the ETC Model;

(7) Require the model participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(8) Discontinue the provision of data sharing and reports to the model participant.

(9) Recoup model-specific payments.

(10) Reduce or eliminate a model-specific payment otherwise owed to the model participant.

(11) Such other action as may be permitted under the terms of this part.

§ 512.165 Innovation center model termination by CMS.

(a) CMS may terminate an Innovation Center model for reasons including, but not limited to, the following:

(1) CMS determines that it no longer has the funds to support the Innovation Center model.

(2) CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

(b) If CMS terminates an Innovation Center model, CMS will provide written notice to the model participant specifying the grounds for model termination and the effective date of such termination.

§ 512.170 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all of the following:

(a) The selection of models for testing or expansion under section 1115A of the Act.

(b) The selection of organizations, sites, or participants, including model participants, to test the Innovation Center models selected, including a decision by CMS to remove a model participant or to require a model participant to remove a downstream participant from the Innovation Center model.

(c) The elements, parameters, scope, and duration of such Innovation Center models for testing or dissemination, including without limitation the following:

(1) The selection of quality performance standards for the Innovation Center model by CMS.

(2) The assessment by CMS of the quality of care furnished by the model participant.

(3) The attribution of model beneficiaries to the model participant by CMS, if applicable.

(d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

(e) The termination or modification of the design and implementation of an Innovation Center model under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of an Innovation Center model under section 1115A(c) of the Act, including the determination that an Innovation Center model is not expected to meet criteria described in paragraph (a) or (b) of such section.

§ 512.180 Miscellaneous provisions on bankruptcy and other notifications.

(a) *Notice of bankruptcy.* If the model participant has filed a bankruptcy petition, whether voluntary or involuntary, the model participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the model participant under the terms of each model tested under section 1115A of the Act in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(b) *Notice of legal name change.* A model participant must furnish written notice to CMS at least 60 days before any change in its legal name becomes effective. The notice of legal name change must be in a form and manner specified by CMS and must include a copy of the legal document effecting the name change, which must be authenticated by the appropriate state official.

(c) *Notice of change in control.* A model participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before any change in control becomes effective. If CMS determines, in accordance with § 512.160(a)(5), that a model participant's change in control would present a program integrity risk, CMS may take remedial action against the model participant under § 512.160(b). CMS may also require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

Subpart B—Radiation Oncology Model

General

§ 512.200 Basis and scope of subpart.

(a) *Basis.* This subpart implements the test of the Radiation Oncology (RO) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other regulations affecting providers and suppliers under Medicare FFS, including the applicability of regulations regarding payment, coverage and program integrity.

(b) *Scope.* This subpart sets forth the following:

(1) RO Model participants.

(2) Episodes being tested under the RO Model.

(3) Methodology for pricing and quality performance.

(4) Payments and billing under the RO Model.

(5) The Model as an Advanced APM and MIPS APM under the Quality Payment Program.

(6) Program waivers issued for RO participant use.

(7) Data reporting requirements.

(8) Payment reconciliation and appeals processes.

(c) *Applicability.* RO participants are subject to the general provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.205 Definitions.

For purposes of this subpart, the following definitions apply:

Aggregate quality score (AQS) means the numeric score calculated for each RO participant based on its performance on, and reporting of, proposed quality measures and clinical data. The AQS is used to determine the amount of a RO participant's quality reconciliation payment amount.

Clean period means the 28-day period after an episode has ended, during which time a RO participant must bill for medically necessary RT services furnished to the RO beneficiary in accordance with Medicare FFS billing rules.

Core Based Statistical Area (CBSA) means a statistical geographic area, based on the definition as identified by the Office of Management and Budget, with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core).

Discount factor means the set percentage by which CMS reduces a participant-specific professional episode payment or a participant-specific technical episode payment after the trend factor and model-specific adjustments have been applied but before beneficiary cost-sharing and standard CMS adjustments, including the geographic practice cost index (GPCI) and sequestration, have been applied. The discount factor does not vary by cancer type. The discount factor for the professional component is 4 percent; the discount factor for the technical component is 5 percent.

Dual participant means a RO participant that furnishes for both the professional component and technical component of RT services of an episode through a freestanding radiation therapy center, identified by a single TIN.

Duplicate RT service means any included RT service that is furnished to a single RO beneficiary by a RT provider or RT supplier that did not initiate the PC or TC of that RO beneficiary during the episode.

Episode means the 90-day period that, as set forth in § 512.245, begins on the date of service that an individual practitioner under a professional participant or a dual participant furnishes an initial RT treatment planning service to a RO beneficiary, provided that a technical participant or the same dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service.

HOPD means hospital outpatient department.

Included cancer types means the cancer types determined by the criteria set forth in § 512.230, which are included in the RO Model test.

Included RT services means the RT services identified at § 512.235, which are included in the RO Model test.

Incomplete episode means the circumstances in which an episode does not occur because—

(1) A Technical participant or a Dual participant does not furnish a technical component to a RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an RT treatment planning service to that RO beneficiary;

(2) Traditional Medicare stops being the primary payer at any point during the relevant 90-day period for the RO beneficiary; or

(3) A RO beneficiary stops meeting the beneficiary population criteria under § 512.215(a) or triggers the beneficiary exclusion criteria under § 512.215(b) before the technical component of an episode initiates.

Individual practitioner means a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and have reassigned their billing rights to the TIN of a RO participant.

Individual practitioner list means a list of individual practitioners who furnish RT services under the TIN of a Dual participant or a Professional participant, which is annually compiled by CMS and which the RO participant must review, revise, and certify in accordance with § 512.217. The individual practitioner list is used for the RO Model as a Participation List as defined in § 414.1305 of this chapter.

Model performance period means, the date the RO Model begins through December 31, 2024, the last date during which episodes under the Model must be completed. No new episodes may begin after October 3, 2024 in order for all episodes to be completed by December 31, 2024.

National base rate means the total payment amount for the relevant component of an episode, before application of the trend factor, discount factor, adjustments, and applicable withholds, for each of the proposed included cancer types.

NPI means National Provider Identifier.

Participant-specific professional episode payment means a payment, which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Professional participant or Dual participant as set forth in § 512.265, for the provision of the professional component to a RO beneficiary during an episode.

Participant-specific technical episode payment means a payment, which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Technical participant or Dual participant in accordance with § 512.265, for the provision of the technical component to a RO beneficiary during an episode.

Performance year (PY) means the 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period.

PGP means physician group practice.

Professional component (PC) means the included RT services that may only be furnished by a physician.

Professional participant means a RO participant that is a Medicare-enrolled PGP identified by a single TIN that furnishes only the PC of an episode.

Radiotherapy (RT) services are the treatment planning, technical preparation, special services (such as simulation), treatment delivery, and treatment management services associated with cancer treatment that use high doses of radiation to kill cancer cells and shrink tumors.

Reconciliation payment means a payment made by CMS to a RO participant, as determined in accordance with § 512.285.

Repayment amount means the amount owed by a RO participant to CMS, as determined in accordance with § 512.260.

RO beneficiary means a Medicare FFS beneficiary who meets all of the beneficiary inclusion criteria at § 512.215(a) and who does not trigger any of the beneficiary exclusion criteria at § 512.215(b).

Reconciliation report means the annual report issued by CMS to a RO participant for each performance year, which specifies the RO participant's reconciliation payment amount or repayment amount.

RO participant means a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to § 512.210. A RO participant may be a Dual participant, Professional participant, or Technical participant.

RT provider means a Medicare-enrolled HOPD that furnishes RT services in a 5-digit ZIP Code linked to a selected CBSA.

RT supplier means a Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services in a 5-digit ZIP Code linked to a selected CBSA.

Selected CBSA means a CBSA that has been randomly-selected by CMS under § 512.210(c).

Technical component (TC) means the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and administrative costs related to RT services.

Technical participant means a RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only for the TC of an episode.

TIN stands for Taxpayer Identification Number.

Trend factor means an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services.

True-up means the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out.

RO Model Participation

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* (1) Unless otherwise specified in paragraph (b) of this section, any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that furnishes included RT services in a 5-digit ZIP Code linked to a selected CBSA to a RO beneficiary for an episode that begins on or after January 1, 2020, and ends on or before December 31, 2024, must participate in the RO Model.

(b) *Participant exclusions.* A PGP, freestanding radiation therapy center, or HOPD will be excluded from participation in the RO Model if it—

(1) Furnishes RT services only in Maryland;

(2) Furnishes RT services only in Vermont;

(3) Furnishes RT services only in U.S. Territories;

(4) Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or

(5) Participates in or is identified by CMS as eligible to participate the Pennsylvania Rural Health Model.

(c) *Selected CBSAs.* CMS randomly selects CBSAs to identify RT providers and RT suppliers to participate in the Model through a stratified sample design, allowing for participant and comparison groups to contain approximately 40 percent of all episodes in eligible geographic areas (CBSAs).

§ 512.215 Beneficiary population.

(a) *Beneficiary inclusion criteria.* (1) Except as provided in paragraph (b) of this section, a beneficiary is included in the RO Model if the beneficiary:

(i) Receives included RT services in a 5-digit ZIP Code linked to a selected CBSA from a RO participant during the model performance period for a cancer type that meets the criteria for inclusion in the RO Model; and

(ii) At the time that the initial treatment planning service of an episode is furnished by an RO participant, the beneficiary—

(A) Is eligible for Medicare Part A and enrolled in Medicare Part B; and

(B) Has traditional FFS Medicare as his or her primary payer.

(2) Any RO beneficiary enrolled in a clinical trial for RT services for which Medicare pays routine costs will be included in the RO Model provided that the beneficiary satisfies all of the beneficiary inclusion criteria in paragraph (a)(1) of this section.

(b) *Beneficiary exclusion criteria.* A beneficiary is excluded from the RO Model if, at the initial treatment planning service the beneficiary is—

(1) Enrolled in any Medicare managed care organization, including but not limited to Medicare Advantage plans;

(2) Enrolled in a PACE plan;

(3) Is in a Medicare hospice benefit period; or

(4) Covered under United Mine Workers.

(c) *Changes during an episode.* (1) If a RO beneficiary stops meeting any of the proposed eligibility criteria before the TC of the episode has been initiated, then the episode is classified as an incomplete episode. Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process.

(2) If traditional Medicare stops being an RO beneficiary's primary payer after the TC of the episode has been initiated then, regardless of whether the beneficiary's course of RT treatment was completed, the 90-day period is considered an incomplete episode and, the RO participant may receive only the first installment of the episode payment. In the event that a RO beneficiary dies or enters hospice during an episode, then the RO participant may receive both installments of the episode payment regardless of whether the RO beneficiary's course of RT has ended.

§ 512.217 Identification of individual practitioners.

(a) *General.* Prior to the start of each performance year, CMS will create and provide to each Dual participant and Professional participant an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant.

(b) *Review of individual practitioner list.* Within 30 days of receipt of such individual practitioner list, the RO participant must review and certify the individual practitioner list in a form and manner specified by CMS and in accordance with paragraph (c) of this section or correct the individual practitioner list in accordance with paragraph (d) of this section.

(c) *List certification.* (1) Within 30 days of receipt of such individual practitioner list, and at such other times as specified by CMS, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge information and belief.

(2) All Medicare-enrolled individual practitioners that have reassigned their right to receive Medicare payment for provision of RT services to the TIN of the RO participant must be included on the RO participant's individual practitioner list and each individual practitioner must agree to comply with the requirements of the RO Model before the RO participant certifies the individual practitioner list.

(d) *Changes to the individual practitioner list*—(1) *Additions.* (i) A RO participant must notify CMS of an addition to its individual practitioner list within 15 days of when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) If the RO participant timely submits notice to CMS, the addition of an individual practitioner to the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS, but no earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice to CMS, the addition of an individual practitioner to the individual practitioner list is effective on the date of the notice.

(2) *Removals.* (i) A RO participant must notify CMS no later than 15 days of when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner. The notice must be submitted in the form and manner specified by CMS.

(ii) The removal of an individual practitioner from the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit a timely notice of the removal, the removal is effective on the date of the notice.

(e) *Update to Medicare enrollment information.* The RO participant must ensure that all changes to enrollment information for an RO participant and its individual practitioners, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516 of this chapter.

§ 512.220 RO participant compliance with RO Model requirements.

(a) *RO participant-specific requirements.* (1) RO participants are required to meet the Model requirements to qualify for the APM Incentive Payment, as applicable.

(2) Each Professional participant and Dual participant must ensure its individual practitioners—

(i) Discuss goals of care with each RO beneficiary before initiating treatment and communicate to the RO beneficiary whether the treatment intent is curative or palliative;

(ii) Adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or, alternatively, document in the medical record the extent of and rationale for any departure from these guidelines;

(iii) Assess each RO beneficiary's tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses;

(iv) Assess the RO beneficiary's performance status as a quantitative measure determined by the physician;

(v) Send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of treatment to coordinate care;

(vi) Discuss with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and

(vii) Perform and document Peer Review (audit and feedback on treatment plans) for 50 percent of new patients in PY1, for 55 percent of new

patients in PY2, for 60 percent of new patients in PY3, for 65 percent of new patients in PY4, and for 70 percent of new patients in PY5 preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment.

(3) At such times and in the form and manner specified by CMS, each Technical participant and Dual participant must annually attest to whether it actively participates in a radiation oncology-specific AHRQ-listed patient safety organization (PSO) (per their PSO Provider Service Agreement).

(b) *CEHRT.* (1) Each RO participant must use CEHRT, and ensure that its individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria codified in § 414.1415(a)(1)(i) of this chapter. Before each performance year, each RO participant must certify in the form and manner and by a deadline specified by CMS that it will use CEHRT throughout such performance year in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1, the RO participant must certify its intent to use CEHRT throughout PY1 in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

§ 512.225 Beneficiary notification.

(a) *General.* Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services that—

(1) The RO participant is participating in the RO Model;

(2) The RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes. If a RO beneficiary declines claims data sharing for care coordination and quality improvement purposes the RO participant must inform CMS within 30 days of receiving notification from the RO beneficiary that the beneficiary is declining to have their claims data shared in that manner; and

(3) Information regarding RO beneficiary cost-sharing responsibilities.

(b) *Form and manner of notification.* Notification of the information specified in paragraph (a) of this section must be carried out by a RO participant by providing each RO beneficiary with a CMS-developed standardized written notice during the RO beneficiary's initial treatment planning session. The RO participants must furnish the notice to the RO beneficiary in the form and manner specified by CMS.

(c) *Applicability of general Innovation Center provisions.* The beneficiary notifications under this section are not descriptive model materials and activities under § 512.120(c). The requirement described in § 512.120(c)(2) shall not apply to the standardized written notice described in paragraph (b) of this section.

Scope of Episodes Being Tested

§ 512.230 Criteria for determining cancer types.

(a) *Included cancer types.* CMS includes in the RO Model test cancer types that satisfy all of the following criteria. The cancer type:

(1) Is commonly treated with radiation; and

(2) Has associated current ICD–10 codes that have demonstrated pricing stability.

(b) *Removing cancer types.* CMS will remove cancer types in the RO Model if it determines:

(1) RT is no longer appropriate to treat a cancer type per nationally recognized, evidence-based clinical treatment guidelines;

(2) CMS discovers a ≥10 percent error in established national baseline rates; or

(3) The Secretary determines a cancer type not to be suitable for inclusion in the Model.

(c) *ICD–10 codes for included cancer types.* CMS displays on the RO Model website no later than 30 days prior to each performance year the ICD–10 diagnosis codes associated with each included cancer type.

§ 512.235 Included RT services.

(a) Only the following RT services furnished using an included modality identified at § 512.240 for an included cancer type are included RT services that are paid for by CMS under § 512.265:

(1) Treatment planning;

(2) Technical preparation and special services;

(3) Treatment delivery; and,

(4) Treatment management.

(b) All other RT services furnished by an RO participant during the model performance period will be subject to Medicare FFS payment rules.

§ 512.240 Included modalities.

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), image-guided RT (IGRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), intraoperative radiotherapy (IORT), proton beam therapy (PBT), and brachytherapy.

§ 512.245 Scope of episodes.

(a) *General.* Any episode that begins on or after January 1, 2020, and ends on or before December 31, 2024, will be part of the RO Model test and subject to the rules under this part.

(b) *Death or election of hospice benefit.* An episode may be included in, and paid for under, the RO Model even if the RO beneficiary dies or enters hospice during the episode. In accordance with § 512.215(c), the RO participant may receive both installments of the episode payment under such circumstances, regardless of whether the RO beneficiary enters hospice before the relevant course of RT treatment has ended.

(c) *Clean periods.* An episode must not be initiated for the same RO beneficiary during a clean period.

Pricing Methodology

§ 512.250 Determination of national base rates.

CMS determines a national base rate for the PC and TC for each included cancer type. National base rates are the historical average cost for an episode of care for each of the included cancer types prior to the model performance period. We exclude those episodes that do not meet the criteria described in § 512.245. From those episodes, we then calculate the amount CMS paid on average to providers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model's national base rates.

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

Before the start of each performance year CMS calculates the amounts for participant-specific professional episode payment amounts and participant-specific technical episode payment amounts for each included cancer type using the following:

(a) *Trend factors.* CMS adjusts the national base rates for the PC and TC of each cancer type by calculating a separate trend factor for the PC and TC of each included cancer type.

(b) *Case mix adjustment.* CMS establishes and applies case mix adjustments to the trended national base rates for the PC and TC of each included cancer type. These adjustments reflect episode characteristics that may be beyond the control of RO participants such as cancer type, age, sex, presence of a major procedure, death during the episode, and presence of chemotherapy.

(c) *Historical experience adjustment.* CMS establishes and applies historical experience adjustments to the national

base rates after the trend factor and case mix adjustment have been applied. The historical experience adjustments reflect each RO participant's actual historical experience.

(d) *Efficiency factor.* The professional historical experience adjustment and technical historical experience adjustment for each RO participant are weighted by an efficiency factor. The RO participants with a professional historical experience adjustment or technical historical experience adjustment with a value equal to or less zero have a different CMS policy factor than those RO participants with a professional or technical historical experience adjustment of more than zero.

(e) *Changes in business structure.* RO participants must notify CMS in writing of a merger, acquisition, or other new clinical or business relationship, at least 90 days before the effective date of the change. CMS updates case mix and historical experience adjustments pursuant to the relevant treatment history that applies as a result of a merger, acquisition, or other new clinical or business relationship in the RO participant's case mix and historical experience adjustment calculations from the effective date of the change.

(f) *HOPD or freestanding radiation therapy center with fewer than 60 episodes during 2015–2017.* If a HOPD, or freestanding radiation therapy center (identified by a CCN or TIN) meets eligibility requirements and begins to provide RT services within a selected CBSA, but has fewer than 60 episodes from 2015 to 2017 to calculate case mix and historical experience adjustments, then its participant-specific professional episode payment amount and participant-specific technical episode payment amount are equal the trended national base rates in PY1. In PY2, if an RO participant with fewer than 60 episodes attributed to it during the 2015 through 2017 period continues to have fewer than 60 episodes attributed to it during the 2016 through 2018 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts would continue to equal the trended national base rates in PY2. However, if the RO participant had 60 or more attributed episodes during the 2016 through 2018 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts for PY2 would equal the trended national base rates with the case mix adjustment added. In PY3 to PY5, we will reevaluate those same RO participants as we did in PY2 to determine the number of episodes in the rolling 3-year period used in the case mix adjustment for that performance year. RO participants that continue to have fewer than 60 attributed episodes in the rolling 3-year period used in the case mix adjustment for that performance year would continue to have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates, whereas those that have 60 or more attributed episodes would have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates with the case mix adjustment added.

(g) *Discount factor.* CMS deducts a percentage discount from the trended national base rates after the case mix and historical experience adjustments have been applied. The discount factor for the PC is 4 percent. The discount factor for TC is 5 percent.

(h) *Incorrect payment withhold.* CMS withholds from each RO participant 2 percent from each episode payment, after the trend factor, adjustments, and discount factor have been applied, in order to account for duplicate RT services and incomplete episodes. CMS determines during the annual reconciliation process set forth at § 512.285 whether a RO participant is eligible to receive a portion or all of the withheld amount or whether any payment is owed to CMS.

(i) *Quality withhold.* CMS withholds 2 percent for the PC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factors are applied to comply with the Advanced APM criteria codified in § 414.1415(b)(1) of this chapter which requires an Advanced APM to include quality measure results as a factor when determining payment to participants under the terms of the APM. RO participants may earn back this withhold, in part or in full, based on their AQS.

(j) *Patient experience withhold.* CMS withholds one percent of the technical episode payment amounts starting in 2022 (PY3) to account for patient experience in the RO Model, which is based on the patient-reported Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) Cancer Care Radiation Therapy survey. RO participants may earn back this withhold, in part or in full, based on their results from the CAHPS® Cancer Care Radiation Therapy survey.

(k) *Geographic adjustment.* CMS further adjusts the trended national base rates that have been adjusted for each RO participant's case mix, historical experience, and after which the discount rate and withholds have been applied, for local cost and wage indices based on where RT services are furnished, pursuant to existing geographic adjustment processes in the OPPS and PFS.

(l) *Coinsurance.* RO participants may collect beneficiary coinsurance payments in multiple installments via a payment plan.

Billing and Payment

§ 512.260 Billing.

(a) *Reassignment of billing rights.* Each Professional participant and Dual participant must ensure that its individual practitioners reassign their billing rights to the TIN of the Professional participant or Dual participant.

(b) *Billing under the RO Model.* (1) Professional participants and Dual participants shall bill a RO Model-specific HCPCS code and a start-of-episode modifier to indicate that the treatment planning service has been furnished and that an episode has been initiated.

(2) Dual participants and Technical participants shall bill a RO model-specific HCPCS code and start-of-episode modifier to indicate that a treatment delivery service was furnished.

(3) RO participant shall bill the same RO Model-specific HCPCS code that initiated the episode and an end-of-episode modifier to indicate that the episode has ended.

(c) *Billing for RT services performed during a clean period.* A RO participant shall bill for any medically necessary RT services furnished to a RO beneficiary during a clean period pursuant to existing FFS billing processes in the OPPS and PFS.

§ 512.265 Payment.

(a) *Payment for episodes.* CMS pays a RO participant for all included RT services furnished to a RO beneficiary during an episode as follows—

(1) CMS pays a Professional participant a participant-specific professional episode payment for the professional component furnished to a RO beneficiary during an episode.

(2) CMS pays a Technical participant a participant-specific technical episode payment for the technical component furnished to a RO beneficiary during an episode.

(3) CMS pays a Dual participant a participant-specific professional episode payment and a participant-specific technical episode payment for the professional component and technical

component furnished to a RO beneficiary during an episode.

(b) *Payment installments.* CMS makes each of the payments described in paragraph (a) of this section in two equal installments, as follows—

(1) CMS pays one-half of a participant-specific professional episode and/or one-half of the participant-specific technical episode payment after the RO participant bills a RO Model-specific HCPCS code with a start-of-episode modifier.

(2) CMS pays the remaining half of a participant-specific professional episode and/or one-half of the participant-specific technical episode payment after the RO participant bills a RO Model-specific HCPCS code with an end-of-episode modifier.

§ 512.270 Treatment of add-on payments under existing Medicare payment systems.

CMS does not make separate Medicare FFS payments to RO participants for any included RT services that are furnished to a RO beneficiary during an episode. A RO participant may receive Medicare FFS payment for items and services furnished to a RO beneficiary during an episode, provided that any such other item or service is not an included RT service.

Data Reporting

§ 512.275 Quality measures, clinical data, and reporting.

(a) *Data privacy compliance.* The RO participant must comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the Innovation Center model, as well as the terms of any agreement entered into by the RO participant with CMS as a condition of receiving that data. These laws include without limitation the standards for the privacy of individually identifiable health information and the security standards for the protection of electronic protected health information under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). The RO participant must bind all downstream recipients of such data in a signed writing to comply with all applicable laws pertaining to patient-identifiable data provided by CMS, as well as the terms of any agreement entered into by the RO participant with CMS as a condition of receiving that data, as a condition of a downstream recipient's receipt of the data from the RO participant and the maintenance thereof.

(b) *Participant public release of patient de-identified information.* The RO participant must include the disclaimer codified at § 512.120(c)(2) on the first page of any publicly-released document, the content of which materially and substantially references or is materially and substantially based upon the RO participant's participation in the RO Model, including but not limited to press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials.

(c) *Professional and Dual participants.* Professional participants and Dual participants must report selected quality measures on all patients and clinical data elements, such as cancer stage, disease involvement, treatment intent and specific treatment plan information on beneficiaries treated for specified cancer types, in the form, manner, and at a time specified by CMS.

Medicare Program Waivers

§ 512.280 RO Model Medicare program waivers.

(a) *General.* The Secretary shall waive certain requirements of title XVIII of the Act as necessary solely for purposes of testing of the RO Model. Such waivers apply only to the participants in the RO Model.

(b) *Hospital Outpatient Quality Reporting (OQR) Program.* CMS waives the application of the Hospital OQR Program 2.0 percentage point reduction under section 1833(t)(17) of the Act for only those Ambulatory Payment Classifications (APCs) that include only RO Model-specific HCPCS codes during the model performance period.

(c) *Merit-based Incentive Payment System (MIPS).* CMS waives the requirement to apply the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) under section 1848(q)(6)(E) of the Act and § 414.1405(e) of this chapter that may otherwise apply to payments made for services furnished by a MIPS eligible clinician and billed under the professional RO Model-specific HCPCS codes.

(d) *APM Incentive Payment.* CMS waives the requirements of § 414.1450(b) such that technical component payment amounts under the RO Model shall not be considered in calculation of the aggregate payment amount for covered professional services as defined in section 1848(k)(3)(A) of the Act for the APM Incentive Payment made under § 414.1450(b)(1).

(e) *PFS Relativity Adjuster.* CMS waives the requirement to apply the PFS Relativity Adjuster to RO Model-specific APCs for RO participants that are non-excepted off-campus provider-based departments (PBDs) identified by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), which amended section 1833(t)(1)(B)(v) and added paragraph (t)(21) to the Social Security Act.

(f) *General payment waivers.* CMS waives the following sections of the Act solely for the purposes of testing the RO Model:

(1) 1833(t)(1)(A).

(2) 1833(t)(16)(D).

(3) 1848(a)(1).

(4) 1869 claims appeals procedures.

Reconciliation

§ 512.285 Reconciliation process.

(a) *General.* CMS uses the reconciliation process described in paragraph (b) of this section after the end of each performance year to identify any reconciliation payment amount owed to a RO participant or any repayment amount owed by a RO participant to CMS.

(b) *Annual reconciliation.* CMS conducts an annual reconciliation for each RO participant in August following each performance year.

(1) *Reconciliation report.* CMS issues each RO participant a reconciliation report for each performance year. Each reconciliation report contains the following:

(i) The determination as to whether the RO participant is eligible for a reconciliation payment or must make a repayment to CMS.

(ii) The RO participant's reconciliation payment amount or repayment amount for the relevant performance year, as calculated by CMS.

(2) *Reconciliation payments.* If a RO reconciliation report indicates that a RO participant has earned a reconciliation payment, then CMS must issue such payment to the RO participant in the amount specified in the reconciliation report as soon as administratively possible after the reconciliation report is deemed final. The RO participant is not permitted to collect any beneficiary cost-sharing with respect to any reconciliation payment received.

(3) *Repayment amounts.* If a final reconciliation report indicates that CMS is owed a repayment amount, then the RO participant must make a payment to CMS in the repayment amount by a deadline specified by CMS. If the RO participant fails to timely pay the full repayment amount, CMS recoups the repayment amount from any payments

otherwise owed by CMS to the RO participant, including Medicare payments for items and services unrelated to the RO Model.

§ 512.290 Timely error notice and reconsideration review process.

(a) *Timely error notice.* Subject to the limitations on review in § 512.170, if the RO participant identifies a suspected error in the calculation of their reconciliation payment or repayment amount or AQS for which a determination has not yet been deemed to be final under the terms of the RO reconciliation report, the RO participant may provide written notice of the suspected calculation error to CMS, in a form and manner and by a date and time specified by CMS.

(1) Unless the RO participant provides such notice, the reconciliation payment or repayment amount determination made under § 512.285(b)(1) is deemed final 30 days after it is issued.

(2) If CMS receives a timely notice of a suspected calculation error, then CMS will respond in writing within 30 days either to confirm that there was an error in the calculation or to verify that the calculation is correct. CMS may extend the deadline for its response upon written notice to the RO participant.

(3) Only the RO participant may use the timely error notice process described in this paragraph and the reconsideration review process described in paragraph (b) of this section.

(4) The RO participant must have submitted a timely error notice on an issue not precluded from administrative or judicial review as a condition of using the reconsideration review process described in paragraph (b) of this section.

(b) *Reconsideration review.* (1) If the RO participant is dissatisfied with CMS's response to the timely error notice, then the RO participant may request a reconsideration review of CMS's response within 10 days of the issue date of CMS' response in a form and manner specified by CMS.

(2) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment or repayment amount or AQS in accordance with the terms of this subpart.

(3) If CMS does not receive a request for reconsideration from the RO participant within 10 days of the issue date of CMS' response to the RO participant's timely error notice, then CMS' response to the timely error notice is deemed final.

(4) CMS designates a reconsideration official, who is a designee of CMS, who is authorized to receive such requests and who was not involved in the responding to the RO participant's timely error notice. The CMS reconsideration official makes reasonable efforts to notify the RO participant and CMS in writing within 15 days of receiving the RO participant's reconsideration review request of the following:

(i) The issues in dispute;

(ii) The briefing schedule; and

(iii) The review procedures.

(5) The CMS reconsideration official makes all reasonable efforts to complete the on-the-record resolution review and issue a written determination no later than 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule.

Subpart C—ESRD Treatment Choices Model

General

§ 512.300 Basis and scope.

(a) *Basis.* This subpart implements the test of the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart must not be construed to affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, or program integrity.

(b) *Scope.* This subpart sets forth the following:

(1) The duration of the ETC Model.

(2) The method for selecting ETC Participants.

(3) The schedule and methodologies for the Home Dialysis Payment Adjustment and Performance Payment Adjustment.

(4) The methodology for ETC Participant performance assessment for purposes of the Performance Payment Adjustment, including beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score.

(5) Monitoring and evaluation, including quality measure reporting.

(6) Medicare payment waivers.

§ 512.310 Definitions.

For purposes of this subpart, the following definitions apply.

Adjusted ESRD PPS per treatment base rate means the per treatment payment amount as defined in § 413.230 of this chapter, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and transitional drug add-on payment adjustment (TDAPA) amount.

Benchmark year means the 12-month period that begins 18 months prior to the start of a given measurement year (MY) from which data is used to construct benchmarks against which to score an ETC Participant's achievement and improvement on the home dialysis rate and transplant rate for the purpose of calculating the ETC Participant's MPS.

Clinician Home Dialysis Payment Adjustment (Clinician HDPA) means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant, for the Managing Clinician's home dialysis claims, as described in §§ 512.345 and 512.350.

Clinician Performance Payment Adjustment (Clinician PPA) means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in §§ 512.375(b) and 512.380.

Comparison geographic area(s) means those HRRs that are not selected geographic areas.

ESRD Beneficiary means a beneficiary receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney or kidney-pancreas transplant.

ESRD facility means an ESRD facility as specified in § 413.171 of this chapter.

ETC Participant means an ESRD facility or Managing Clinician that is required to participate in the ETC Model pursuant to § 512.325(a).

Facility home dialysis payment adjustment (Facility HDPA) means the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in §§ 512.340 and 512.350.

Facility performance payment adjustment (Facility PPA) means the payment adjustment to the Adjusted ESRD PPS per treatment base rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in §§ 512.375(a) and 512.380.

Home dialysis payment adjustment (HDPA) means either the Facility HDPA or the Clinician HDPA.

Home dialysis rate means the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b).

Hospital referral regions (HRRs) means the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at *https://www.dartmouthatlas.org/.*

Managing clinician means a Medicare-enrolled physician or non-physician practitioner who furnishes and bills the MCP for managing one or more adult ESRD beneficiaries.

Measurement year (MY) means the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Each MY included in the ETC Model and its corresponding PPA Period are specified in § 512.355(c).

Modality performance score (MPS) means the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in § 512.370(d), which is used to determine the amount of the ETC Participant's PPA, as described in § 512.380.

Monthly capitation payment (MCP) means the monthly capitated payment made for each ESRD Beneficiary to cover all routine professional services related to treatment of the patient's renal condition furnished by the physician or non-physician practitioner as specified in § 414.314 of this chapter.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

Performance payment adjustment (PPA) means either the Facility PPA or the Clinician PPA.

Performance payment adjustment period (PPA Period) means the six-month period during which a PPA is applied pursuant to § 512.380.

Pre-emptive transplant beneficiary means a beneficiary who received a kidney or kidney-pancreas transplant prior to beginning dialysis.

Selected geographic area(s) are those HRRs selected by CMS pursuant to § 512.325(b) for purposes of selecting ESRD facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants.

Subsidiary ESRD Facility is an ESRD facility owned in whole or in part by another legal entity.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1.

Transplant rate means the rate of ESRD beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC Participant who received a kidney or kidney-pancreas transplant during the MY, as described in § 512.365(c).

ESRD Treatment Choices Model Scope and Participants

§ 512.320 Duration.

CMS will apply the payment adjustments described in this subpart under the ETC Model to claims with claim through dates beginning January 1, 2020, and ending June 30, 2026.

§ 512.325 Participant selection and geographic areas.

(a) *Selected participants.* All Medicare-certified ESRD facilities and Medicare-enrolled Managing Clinicians located in a selected geographic area are required to participate in the ETC Model.

(b) *Selected geographic areas.* CMS establishes the selected geographic areas by selecting a random sample of 50 percent of HRRs, stratified by Census-defined regions (Northeast, South, Midwest, and West), as well as all HRRs for which at least 20 percent of the component zip codes are located in Maryland. CMS excludes all U.S. Territories from the selected geographic areas.

§ 512.330 Beneficiary notification.

(a) *General.* ETC Participants must prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. CMS provides the ETC Participant with a template for these materials, indicating the required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content.

(b) *Applicability of general Innovation Center model provisions.* The requirement described in § 512.120(c) shall not apply to the CMS-provided materials described in paragraph (a) of this section. All other ETC Participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

Home Dialysis Payment Adjustment

§ 512.340 Payments subject to the facility HDPA.

CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA on claim lines with Type of Bill 072X, and with condition codes 74, 75, 76, or 80, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim through date during a calendar year (CY) subject to adjustment as described in § 512.350 and the beneficiary is 18 years of age or older during the entire month of the claim.

§ 512.345 Payments subject to the clinician HDPA.

CMS adjusts the amount otherwise paid under Part B with respect to MCP claims on claim lines with CPT codes 90965 and 90966 by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant with a claim through date during a CY subject to adjustment as described in § 512.350 and the beneficiary is 18 years of age or older during the entire month of the claim.

§ 512.350 Schedule of home dialysis payment adjustments.

CMS adjusts the payments specified in § 512.340 by the Facility HDPA and adjusts the payments specified in § 512.345 by the Clinician HDPA, according to the following schedule:

(a) CY 2020: +3 percent

(b) CY 2021: +2 percent

(c) CY 2022: +1 percent

Performance Payment Adjustment

§ 512.355 Schedule of performance assessment and performance payment adjustment.

(a) *Measurement Years.* CMS assesses ETC Participant performance on the home dialysis rate and the transplant rate during each of the MYs. The first MY begins on January 1, 2020, and the final MY ends on June 30, 2025.

(b) *Performance Payment Adjustment Period.* CMS adjusts payments for ETC Participants by the PPA during each of the PPA Periods, each of which corresponds to a MY. The first PPA Period begins on July 1, 2021, and the final PPA Period ends on June 30, 2026.

(c) *Measurement Years and Performance Payment Adjustment Periods.* MYs and PPA Periods follow the schedule in Table 1 to § 512.355(c):

TABLE 1 to § 512.355(c)--ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

Model Year	Measurement Year (MY)	Performance Payment Adjustment (PPA) Period
Beginning CY 2020	MY 1 – 1/1/2020 through 12/31/2020	PPA Period 1 – 7/1/2021 through 12/31/2021
	MY 2 – 7/1/2020 through 6/30/2021	PPA Period 2 – 1/1/2022 through 6/30/2022
Beginning CY 2021	MY 3 – 1/1/2021 through 12/31/2021	PPA Period 3 – 7/1/2022 through 12/31/2022
	MY 4 – 7/1/2021 through 6/30/2022	PPA Period 4 –1/1/2023 through 6/30/2023
Beginning CY 2022	MY 5 – 1/1/2022 through 12/31/2022	PPA Period 5 – 7/1/2023 through 12/31/2023
	MY 6 – 7/1/2022 through 6/30/2023	PPA Period 6 –1/1/2024 through 6/30/2024
Beginning CY 2023	MY 7 – 1/1/2023 through 12/31/2023	PPA Period 7 – 7/1/2024 through 12/31/2024
	MY 8 – 7/1/2023 through 6/30/2024	PPA Period 8 – 1/1/2025 through 6/30/2025
Beginning CY 2024	MY 9 – 1/1/2024 through 12/31/2024	PPA Period 9 – 7/1/2025 through 12/31/2025
	MY 10 – 7/1/2024 through 6/30/2025	PPA Period 10 – 1/1/2026 through 6/30/2026

§ 512.360 Beneficiary population and attribution.

(a) *General.* Except as provided in paragraph (b) of this section, CMS attributes ESRD Beneficiaries to an ETC Participant for each month during a MY based on the ESRD Beneficiary's receipt of services specified in paragraph (c) of this section during that month, for the purpose of assessing the ETC Participant's performance on the home dialysis rate and transplant rate during that MY. Except as provided in paragraph (b) of this section, CMS attributes pre-emptive transplant beneficiaries to a Managing Clinician for one or more months during a MY based on the pre-emptive transplant beneficiary's receipt of services specified in paragraph (c)(2) of this section during that month, for the purpose of assessing the Managing Clinician's performance on the transplant rate during that MY. CMS attributes ESRD Beneficiaries and pre-emptive transplant beneficiaries to the ETC Participant for each month during a MY after the end of the MY. CMS attributes an ESRD Beneficiary to no more than one ESRD facility and no more than one Managing Clinician for a given month during a given MY; CMS attributes a pre-emptive transplant beneficiary to no more than one Managing Clinician for a given MY.

(b) *Exclusions from attribution.* CMS does not attribute an ESRD Beneficiary or a pre-emptive transplant beneficiary to an ETC Participant for a month if, at any point during the month, the ESRD Beneficiary or the pre-emptive transplant beneficiary—

(1) Is not enrolled in Medicare Part B;

(2) Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plan;

(3) Does not reside in the United States;

(4) Is younger than 18 years of age;

(5) Has elected hospice;

(6) Is receiving dialysis for acute kidney injury (AKI) only; or

(7) Has a diagnosis of dementia.

(c) *Attribution services*—(1) *ESRD facility beneficiary attribution.* To be attributed to an ESRD facility that is an ETC Participant for a month, an ESRD Beneficiary must have received renal dialysis services, other than renal dialysis services for AKI, during the month from the ESRD facility. An ESRD Beneficiary is attributed to the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month, as identified by claims with Type of Bill 072X, with claim through dates during the month. If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, CMS attributes the ESRD Beneficiary to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month. CMS does not attribute pre-emptive transplant beneficiaries to ESRD facilities.

(2) *Managing clinician beneficiary attribution.* An ESRD Beneficiary is attributed to a Managing Clinician who is an ETC Participant for a month if that Managing Clinician submitted an MCP claim for services furnished to the beneficiary, identified with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, with claim through dates during the month. A pre-emptive transplant beneficiary is attributed to the Managing Clinician with whom the beneficiary had the most claims between the start of the MY and the month in which the beneficiary received the transplant for all months between the start of the MY and the month of the transplant.

§ 512.365 Performance assessment.

(a) *General.* For each MY, CMS separately assesses the home dialysis rate and the transplant rate for each ETC Participant based on the population of ESRD Beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC Participant under § 512.360. Information used to calculate the home dialysis rate and the transplant rate includes Medicare claims data, Medicare administrative data, and data from the Scientific Registry of Transplant Recipients.

(b) *Home dialysis rate.* CMS calculates the home dialysis rate for ESRD facilities and Managing clinicians as follows.

(1) *ESRD facilities.* The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is composed of 12 beneficiary months. Months during which attributed ESRD Beneficiaries received maintenance dialysis are identified by claims with Type of Bill 072X. The numerator is the total number of home dialysis treatment beneficiary years for attributed beneficiaries during the MY. Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with Type of Bill 072X and condition codes 74, 75, 76, or 80. Information used to calculate the ESRD facility home

dialysis rate includes Medicare claims data and Medicare administrative data. The ESRD facility home dialysis rate is risk adjusted, as described in paragraph (d)(1) of this section, and reliability adjusted, as described in paragraph (e)(1) of this section.

(2) *Managing clinicians.* The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. The numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Home dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with CPT codes 90965 or 90966. Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data. The Managing Clinician home dialysis rate is risk adjusted, as described in paragraph (d)(1) of this section, and reliability adjusted, as described in paragraph (e)(2) of this section.

(c) *Transplant rate.* CMS calculates the transplant rate for ETC Participants as follows.

(1) *ESRD facilities.* The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month or were in a skilled nursing facility at any point during the month. The numerator is the total number of attributed ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant at any time during the MY. Kidney transplants and kidney-pancreas transplants are identified using claims with MS–DRG 008 or 652; claims with ICD–10 procedure codes 0TY00Z0, 0TY00Z1, 0TY00Z2, 0TY10Z0, 0TY10Z1, or 0TY10Z2; and information about transplants from the SRTR Database and Medicare administrative data to identify any transplants among attributed beneficiaries that are not identified through claims. The ESRD facility transplant rate is risk adjusted, as described in paragraph (d)(2) of this section, and reliability adjusted, as described in paragraph (e)(1) of this section.

(2) *Managing clinicians.* The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, plus the total number of attributed beneficiary years for pre-emptive transplant beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month or were in a skilled nursing facility during the month. Beneficiary years for pre-emptive transplant beneficiaries included in the denominator are composed of those months during which a pre-emptive transplant beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. The numerator is the total number of attributed ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY, plus the number of pre-emptive transplant beneficiaries attributed to the Managing Clinician for the MY. ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant are identified using claims with MS–DRG 008 or 652; claims with ICD–10 procedure codes 0TY00Z0, 0TY00Z1, 0TY00Z2, 0TY10Z0, 0TY10Z1, or 0TY10Z2; and information about transplants from the SRTR Database to identify any transplants among attributed beneficiaries that are not identified through claims. The Managing Clinician transplant rate is risk adjusted, as described in paragraph (d)(2) of this section, and reliability adjusted, as described in paragraph (e)(2) of this section.

(d) *Risk adjustment.* CMS risk adjusts the home dialysis rate using the methodology described in paragraph (d)(1) of this section and risk adjusts the transplant rate using the methodology described in paragraph (d)(2) of this section.

(1) The home dialysis rate for Managing Clinicians and ESRD facilities is risk adjusted using the most recent final risk score for the beneficiary available at the time of the calculation of the home dialysis rate, calculated using the CMS–HCC (Hierarchical Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program.

(2) The transplant rate is risk adjusted by beneficiary age with separate risk coefficients for the following age categories of beneficiaries, with age computed on the last day of each month of the MY: 18 to 55; 56 to 70; and 71 to 74. The transplant rate is adjusted to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution.

(e) *Reliability adjustment.* (1) *ESRD facilities.* An ERSD facility's home dialysis rate and transplant rate are each reliability adjusted such that the ESRD facility's adjusted rate is the weighted average of the ESRD facility's rate and the rate of all ESRD facilities in the ESRD facility's aggregation group, weighted based on the reliability of the ESRD facility's rate. The aggregation group for a subsidiary ESRD facility includes all ESRD facilities owned in whole or in part by the same legal entity located in the HRR in which the ESRD facility is located. The aggregation group for an ESRD facility that is not a subsidiary ESRD facility includes all ESRD facilities located in the HRR in which the ESRD facility is located, with the exception of subsidiary ESRD facilities.

(2) *Managing clinicians.* A Managing clinician's home dialysis rate and transplant rate are each reliability adjusted such that the Managing clinician's adjusted rate is the weighted average of the Managing clinician's rate and the rate of all Managing clinicians in the Managing clinician's aggregation group, based on the reliability of the Managing clinician's rate. Home dialysis

rates and transplant rates are first grouped at the practice group level, as identified by practice TIN, for Managing clinicians who are in a group practice, and at the individual NPI level for Managing clinician who are solo practitioners. Performance is then aggregated to the aggregation group level. The aggregation group for Managing clinicians in a group practice is all Managing clinicians within the HRR in which the group practice is located. The aggregation group for Managing clinicians who are solo practitioners is all Managing clinicians within the HRR in which the Managing clinician is located.

§ 512.370 Benchmarking and scoring.

(a) *General.* CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an achievement score, as described in paragraph (b) of this section. CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an improvement score, as described in paragraph (c) of this section. CMS calculates the ETC Participant's MPS as the weighted sum of the higher of the achievement score or the improvement score for the ETC Participant's home dialysis rate and transplant rate, as described in paragraph (d) of this section. The ETC Participant's MPS determines the ETC Participant's PPA, as described in § 512.380.

(b) *Achievement scoring.* CMS assesses ETC Participant performance on the home dialysis rate and transplant rate against benchmarks constructed based on the home dialysis rate and transplant rate among ESRD facilities and Managing Clinicians located in comparison geographic areas during the benchmark year. CMS uses the following scoring methodology to assess an ETC Participant's achievement score.

(1) *90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 2 points.

(2) *75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 1.5 points.

(3) *50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 1 point.

(4) *30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 0.5 points.

(5) *<30th Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 0 points.

(c) *Improvement scoring.* CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's historical performance on the home dialysis rate and transplant rate during the benchmark year. CMS uses the following scoring methodology to assess an ETC Participant's improvement score.

(1) *Greater than 10 percent improvement relative to the benchmark year rate:* 1.5 points.

(2) *Greater than 5 percent improvement relative to the benchmark year rate:* 1 point.

(3) *Greater than 0 percent improvement relative to the benchmark year rate:* 0.5 points.

(4) *Less than or equal to the benchmark year rate:* 0 points.

(d) *Modality Performance Score.* CMS calculates the ETC Participant's MPS as the higher of ETC Participant's achievement score or improvement score for the home dialysis rate, together with the higher of the ETC Participant's achievement score or improvement score for the transplant rate, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS:

Modality Performance Score = 2 × *(Higher of home dialysis rate achievement or improvement score)* + *(Higher of transplant rate achievement or improvement score)*

§ 512.375 Payments subject to adjustment.

(a) *Facility PPA.* CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility PPA on claim lines with Type of Bill 072X, when the claim is submitted by an ETC Participant that is an ESRD facility and the beneficiary is 18 years of age or older during the entire month of the claim, on claims with claim through dates during the applicable PPA Period as described in § 512.355(c).

(b) *Clinician PPA.* CMS adjusts the amount otherwise paid under Part B with respect to MCP claims on claim lines with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965 and 90966 by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is 18 years of age or older during the entire month of the claim, on claims with claim through dates during the applicable PPA Period as described in § 512.355(c).

§ 512.380 PPA amounts and schedules.

CMS adjusts the payments described in § 512.375 based on the ETC Participant's MPS calculated as described in § 512.370(d) according to the amounts and schedules in Tables 1 and 2 to § 512.380.

TABLE 1 to § 512.380 –FACILITY PPA AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-4.0%	-4.5%	-5.0%	-6.0%	-6.5%
	≤ .5	-8.0%	-9.0%	-10.0%	-12.0%	-13.0%

TABLE 2 to § 512.380 – CLINICIAN PPA AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-3.0%	-3.5%	-4.0%	-4.5%	-5.5%
	≤ .5	-6.0%	-7.0%	-8.0%	-9.0%	-11.0%

§ 512.385 PPA exclusions.

(a) *ESRD facilities.* CMS excludes an ESRD facility that has fewer than 11 attributed beneficiary-years during a MY from the applicability of the Facility PPA for the corresponding PPA Period.

(b) *Managing Clinicians.* CMS excludes a Managing Clinician who falls below the low-volume threshold described in this paragraph during a MY from the applicability of the Clinician PPA for the corresponding PPA Period. The low-volume threshold is set at the bottom 5 percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinician billed the MCP during the MY.

§ 512.390 Notification and targeted review

(a) *Notification.* CMS will notify each ETC Participant, in a form and manner determined by CMS, of the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period no later than one month before the start of the applicable PPA Period.

(b) *Targeted review process.* An ETC Participant may request a targeted review of the calculation of the MPS. Requests for targeted review are limited to the calculation of the MPS, and may not be submitted in regards to: The methodology used to determine the MPS; or the establishment of the home dialysis rate methodology, transplant rate methodology, achievement and improvement benchmarks and benchmarking methodology, or PPA amounts. The process for targeted reviews is as follows:

(1) An ETC Participant has 60 days to submit a request for a targeted review, which begins on the day CMS makes available the MPS.

(2) CMS will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted.

(3) The ETC Participant may include additional information in support of the request for targeted review at the time the request is submitted. If CMS requests additional information from the ETC Participant, it must be provided and received within 30 days of the request. Non-responsiveness to the request for additional information may result in the closure of the targeted review request.

(4) If, upon completion of a targeted review, CMS finds that there was an error in the calculation of the ETC Participant's MPS such that an incorrect PPA has been applied during the PPA period, CMS shall notify the ETC Participant and must resolve any resulting discrepancy payment that arises from the application of an incorrect PPA during the next PPA period that begins after the notification of the ETC Participant.

(5) Decisions based on targeted review are final, and there is no further review or appeal.

Quality Monitoring

§ 512.395 Quality measures.

CMS collects data on the two quality measures below for ESRD facilities that are ETC Participants to monitor for changes in quality outcomes. CMS conducts data collection and measure calculation using claims data and other Medicare administrative data, including enrollment data:

(a) Standardized Mortality Ratio (SMR); NQF #0369.

(b) Standardized Hospitalization Ratio (SHR); NQF #1463.

Medicare Program Waivers

§ 512.397 ETC Model Medicare program waivers.

The following provisions are waived solely for purposes of testing the ETC Model.

(a)(1) *Medicare payment waivers.* CMS waives the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act only to the extent necessary to make the payment adjustments under the ETC Model described in this subpart.

(2) *Beneficiary cost sharing.* The payment adjustments under the ETC Model described in this subpart do not affect the beneficiary cost-sharing amounts for Part B services furnished by ETC Participants under the ETC Model.

(b) *Kidney Disease Education (KDE) benefit waivers.* CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(c)(2)(i) of this chapter to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing clinician who is an ETC Participant;

(2) CMS waives the requirement that the KDE is covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of receiving a diagnosis of ESRD to receive the KDE benefit;

(3) CMS waives the requirement that the content of the KDE sessions include the management of co-morbidities, including delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary;

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about chronic kidney disease and its treatment be performed by a qualified clinician as part of one of the KDE sessions under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed within one month of the final KDE session by qualified staff.

Dated: July 2, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: July 9, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–14902 Filed 7–10–19; 4:45 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, and 484

Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, and 484

[CMS–1711–P]

RIN 0938–AT68

Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the home health prospective payment system (HH PPS) payment rates and wage index for CY 2020; implement the Patient-Driven Groupings Model (PDGM), a revised case-mix adjustment methodology, for home health services beginning on or after January 1, 2020. This proposed rule also implements a change in the unit of payment from 60-day episodes of care to 30-day periods of care, as required by section 51001 of the Bipartisan Budget Act of 2018, hereinafter referred to the ''BBA of 2018'', and proposes a 30-day payment amount for CY 2020. Additionally, this proposed rule proposes to: Modify the payment regulations pertaining to the content of the home health plan of care; allow physical therapy assistants to furnish maintenance therapy; and change the split percentage payment approach under the HH PPS. This proposed rule would also solicit comments on the wage index used to adjust home health payments and suggestions for possible updates and improvements to the geographic adjustment of home health payments. In addition, it proposes public reporting of certain performance data under the Home Health Value-Based Purchasing (HHVBP) Model. We are proposing to publicly report the Total Performance Score (TPS) and the TPS Percentile Ranking from the Performance Year 5 (CY 2020) Annual TPS and Payment Adjustment Report for each home health agency in the nine Model states that qualified for a payment adjustment for CY 2020. It also proposes changes with respect to the Home Health Quality Reporting Program to remove one measure, to adopt two new measures, modify an existing measure, adopt new standardized patient assessment data beginning with the CY 2022 HH QRP, codify the HH QRP policies in a new section, and to remove question 10 from all the HH Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. Lastly, it would set forth routine updates to the home infusion therapy payment rates for CY 2020 and propose payment provisions for home infusion therapy services for CY 2021 and subsequent years.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 9, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1711–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1711–P, 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–1711–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kelly Vontran, (410) 786–0332, for Home Health Prospective Payment System (HH PPS) or home infusion payment.

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), send your inquiry via email to *HHQRPquestions@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Table of Contents

I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2020, as required under section 1895(b) of the Social Security Act (the Act). This proposed rule would also update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care beginning on or after January 1, 2020. This rule would also implement the PDGM, a revised case-mix adjustment methodology that was finalized in the CY 2019 HH PPS final rule (83 FR 56406), which would also implement the removal of therapy thresholds for payment as required by section 1895(b)(4)(B)(ii) of the Act, as amended by section 51001(a)(3) of the BBA of 2018, and changes the unit of home health payment from 60-day episodes of care to 30-day periods of care, as required by section 1895(b)(2)(B) of the Act, as amended by 51001(a)(1) of the BBA of 2018. This proposed rule also proposes to allow therapist assistants to furnish maintenance therapy; proposes changes to the payment regulations pertaining to the content of the home health plan of care; proposes technical regulations text changes clarifying the split-percentage payment approach for newly-enrolled HHAs in CY 2020 and proposes a change in the split percentage payment approach for existing HHAs in CY 2020 and subsequent years.

2. HHVBP

This rule proposes public reporting of the TPS and the TPS Percentile Ranking from the Performance Year 5 (CY 2020) Annual TPS and Payment Adjustment Report for each HHA that qualifies for a payment adjustment under the HHVBP Model for CY 2020.

3. HH QRP

This rule purposes changes to the Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act.

4. Home Infusion Therapy

This proposed rule would update the CY 2020 payment rates for the temporary transitional payment for home infusion therapy services as required by section 1834(u)(7) of the Act, as added by section 50401 of the BBA of 2018. This rule also proposes payment provisions for home infusion therapy services for CY 2021 and subsequent years in accordance with section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114–255).

B. Summary of the Major Provisions

1. Home Health Prospective Payment System (HH PPS)

Section III.A. of this rule, sets forth planned implementation of the Patient-Driven Groupings Model (PDGM) as required by section 51001 of the BBA of 2018 (Pub. L. 115–123). The PDGM is an alternate case-mix adjustment methodology to adjust payments for home health periods of care beginning on and after January 1, 2020. The 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 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018. Section III.B. of this rule also implements a change in the unit of payment from a 60-day episode of care to a 30-day period of care as required by section 1895(b)(2) of the Act, as amended by section 51001(a)(1) of the BBA of 2018.

Section III.C. of this proposed rule describes the CY 2020 case-mix weights for those 60-day episodes that span the implementation date of the PDGM and section III.D. of this proposed rule proposes the CY 2020 PDGM case-mix weights and LUPA thresholds for 30-day periods of care. In section III.E. of this proposed rule, we propose to update the home health wage index and to update the national, standardized 60-day episode of care and 30-day period of care payment amounts, the national per-visit payment amounts as well and the non-routine supplies (NRS) conversion factor for 60-day episodes of care that begin in 2019 and span the 2020 implementation date of the PDGM. The home health payment update percentage for CY 2020 will be 1.5 percent, as required by section 53110 of the BBA of 2018. We also solicit comments on concerns stakeholders may have regarding the wage index used to adjust home health payments and suggestions for possible updates and improvements to the geographic adjustment of home health payments. Section III.F. of this proposed rule proposes a change to the fixed-dollar loss ratio to 0.63 for CY 2020 under the PDGM in order to ensure that outlier payments as a percentage of total payments is closer to, but no more than, 2.5 percent, as required by section 1895(b)(5)(A) of the Act. Section III.G. of this proposed rule, proposes a technical regulations text correction at § 484.205 regarding split-percentage payments for newly-enrolled HHAs in CY 2020; proposes changes to reduce the split-percentage payment amounts for existing HHAs in CY 2020; and proposes to eliminate split-percentage payments entirely beginning in CY 2021. In section III.H. of this proposed rule, we propose to allow physical therapist assistants to furnish maintenance therapy under the Medicare home health benefit, and section III.I. of this proposed proposes a change in the payment regulations at

§ 409.43 related to home health plan of care requirements for payment.

2. HHVBP

In section IV. of this proposed rule, we are proposing to publicly report performance data for Performance Year (PY) 5 of the HHVBP Model. Specifically, we are proposing to publicly report the TPS and the TPS Percentile Ranking from the PY 5 (CY 2020) Annual TPS and Payment Adjustment Report for each HHA in the nine Model states that qualified for a payment adjustment for CY 2020.

3. HH QRP

In section V. of this rule, we propose updates to the Home Health Quality Reporting Program (HH QRP) including: The removal of one quality measure, the adoption of two new quality measures, the modification of an existing measure, and the reporting of standardized patient assessment data described under section 1899B(b)(1)(B) of the Act. In section V.J. of this rule, we are proposing to codify HH QRP policies in a newly created section of the regulations. Finally, in section V.K. of the rule we propose removing question 10 from all HHCAHPS Surveys (both mail surveys and telephone surveys).

4. Home Infusion Therapy

In section VI.A. of this proposed rule, we discuss general background of home infusion therapy services and how that will relate to the implementation of the new home infusion benefit in CY 2021. Section VI.B. of this proposed rule updates the CY 2020 home infusion therapy services temporary transitional payment rates, in accordance with section 1834(u)(7) of the Act. In section VI.C. of this proposed rule, we are proposing to add a new subpart P under the regulations at 42 CFR part 414 to incorporate conforming regulations text regarding conditions for payment for home infusion therapy services for CY 2021 and subsequent years. Proposed subpart P would include beneficiary qualifications and plan of care requirements in accordance with section 1861(iii) of the Act. In section VI.D. of this proposed rule, we propose payment provisions for the full implementation of the home infusion therapy benefit in CY 2021 upon expiration of the home infusion therapy services temporary transitional payments in CY 2020. The home infusion therapy services payment system is to be implemented starting in CY 2021, as mandated by section 5012 of the 21st Century Cures Act. The provisions in this section include proposed payment categories, amounts, and required and optional payment adjustments. In section VI.E. of this proposed rule, we propose to use the Geographic Adjustment Factor (GAF) to wage adjust the home infusion therapy payment as required by section 1834(u)(1)(B)(i) of the Act. In this section VI.F. of this proposed rule, we offer a discussion on several topics for home infusion therapy services for CY 2021 such as: Optional payment adjustments, prior authorization, and high-cost outliers. Lastly, in section VI.H. of this proposed rule, we discuss billing procedures for CY 2021 home infusion therapy services.

C. Summary of Costs, Transfers, and Benefits

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TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2020 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated $250 million (1.3 percent) in increased payments to HHAs in CY 2020.	To ensure home health payments are consistent with statutory payment authority for CY 2020.
CY 2020 HHVBP Model		The overall economic impact of the HHVBP Model for CYs 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. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	
New HH QRP requirements	The total addition in costs beginning in CY 2021 for HHAs as a result of the new quality reporting requirements is estimated to be $169.9 million.		
CY 2020 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 to be either a $1 million increase or decrease in payments to home infusion therapy suppliers in CY 2020 depending upon any changes to Physician Fee Schedule payment amounts for such services.	To ensure temporary transitional payments for home infusion therapy are consistent with statutory authority for CY 2020.
CY 2021 Payments for Home Infusion Therapy Services		The overall economic impact of the payments for home infusion therapy services is an estimated $3 million in decreased payments to eligible home infusion therapy suppliers in CY 2021.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2021.

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II. Overview of the Home Health Prospective Payment System

A. Statutory 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 Social Security Act (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 required 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 required 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 area 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 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 proposed rule.

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 Outcome and Assessment Information Set (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. New Home Health Prospective Payment System for CY 2020 and Subsequent Years

In the CY 2019 HH PPS final rule (83 FR 56446), we finalized a new patient case-mix adjustment methodology, the Patient-Driven Groupings Model (PDGM), to shift the focus from volume of services to a more patient-driven model that relies on patient characteristics. For home health periods of care beginning on or after January 1, 2020, the PDGM uses timing, admission source, principal and other diagnoses, and functional impairment to case-mix adjust payments. The PDGM results in 432 unique case-mix groups. Low-utilization payment adjustments (LUPAs) will vary; instead of the current four visit threshold, each of the 432 case-mix groups has its own threshold to determine if a 30-day period of care

would receive a LUPA. Additionally, non-routine supplies (NRS) are included in the base payment rate for the PDGM instead of being separately adjusted as in the current HH PPS. Also in the CY 2019 HH PPS final rule, we finalized a change in the unit of home health payment from 60-day episodes of care to 30-day periods of care, and eliminated the use of therapy thresholds used to adjust payments in accordance with section 51001 of the BBA of 2018. Thirty-day periods of care will be adjusted for outliers and partial episodes as applicable. For LUPAs under the PDGM, we finalized that the LUPA threshold would vary for a 30-day period under the PDGM using 10th percentile value of visits to create a payment group specific LUPA threshold with a minimum threshold of at least 2 visits for each payment group. Finally, for CYs 2020 through 2022, home health services provided to beneficiaries residing in rural counties will be increased based on rural county classification (high utilization; low population density; or all others) in accordance with section 50208 of the BBA of 2018.

D. Analysis of FY 2017 HHA Cost Report Data for 60-Day Episodes and 30-Day Periods

In the CY 2019 HH PPS proposed rule (83 FR 32348), we provided a summary of analysis on fiscal year (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. We stated in the CY 2019 HH PPS final rule (83 FR 56414) that we will continue to monitor the impacts due to policy changes and will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center web page.

In this year's proposed rule, we examined FY 2017 HHA cost reports as this is the most recent and complete cost report data at the time of rulemaking. We examined the estimated 60-day episode costs using FY 2017 cost reports and CY 2017 home health claims and the estimated costs for 60-day episodes by discipline and the total estimated cost for a 60-day episode for 2017 is shown in Table 2.

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TABLE 2: ESTIMATED COSTS FOR 60-DAY EPISODES IN CY 2017

Discipline	FY2017 Cost Per Visit [1]	Average # Total Visits [2]	60-Day Episode Costs [3]	NRS Cost Per Visit	60-Day Episode Costs with NRS
Skilled Nursing	$135.93	8.59	$1,167.64	$3.58	$1,198.39
Physical Therapy	$156.59	5.78	$905.09	$3.58	$925.78
Occupational Therapy	$153.13	1.7	$260.32	$3.58	$266.41
Speech Pathology	$169.89	0.35	$59.46	$3.58	$60.71
Medical Social Services	$223.96	0.14	$31.35	$3.58	$31.85
Home Health Aides	$61.83	1.63	$100.78	$3.58	$106.62
Total			**$2,524.64**		**$2,589.76**

[1] **Source:** Updated methodology described in the 2013 Rebasing Report using cost reports pulled in January 2019 and claims data from 2016 and 2017.

[2] **Source:** Home health episode data linked to OASIS assessments for episodes ending in CY 2017. PEP and LUPA episodes were excluded. Data derived from average of average total number of visits and average covered number of visits.

[3] **Source:** Calculated by multiplying Average Cost per Visit by Average Number of Total Visits.

To estimate the costs for CY 2020, we updated the estimated 60-day episode costs with NRS by the home health market basket update, minus the multifactor productivity adjustment for CYs 2018 and 2019. For CY 2020, the BBA of 2018 requires a market basket update of 1.5 percent. The estimated costs for 60-day episodes by discipline and the total estimated cost for a 60-day episode for CY 2020 is shown in Table 3.

TABLE 3: ESTIMATED 60-DAY EPISODE COSTS IN CY 2020

Discipline	2017 60-day Episode Costs with NRS	2018 Market Basket Update minus MFP	2019 Market Basket Update minus MFP	2020 Market Basket Update (statutory)	2020 Estimated 60-Day Costs
Skilled Nursing	$1,198.39	1.01	1.022	1.015	$1,255.56
Physical Therapy	$925.78	1.01	1.022	1.015	$969.94
Occupational Therapy	$266.41	1.01	1.022	1.015	$279.12
Speech Pathology	$60.71	1.01	1.022	1.015	$63.61
Medical Social Services	$31.85	1.01	1.022	1.015	$33.37
Home Health Aides	$106.62	1.01	1.022	1.015	$111.71
Total	**$2,589.76**	1.01	1.022	1.015	**$2,713.30**

The CY 2019 60-day episode payment is $3,154.27. Updating this payment amount by the CY 2020 home health market basket of 1.5 percent results in an estimated CY 2020 60-day episode payment of $3,201.58, approximately 18

percent more than the estimated CY 2020 60-day episode cost of $2,713.30. Next, we also looked at the estimated costs for 30-day periods of care in 2017 using FY 2017 cost reports and CY 2017 claims. Thirty-day periods were simulated from 60-day episodes and we excluded low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes. The 30-day periods were linked to OASIS assessments and covered the 60-day episodes ending in CY 2017. The estimated costs for 30-day periods by discipline and the total estimated cost for a 30-day period for 2017 is shown in Table 4.

TABLE 4: ESTIMATED COSTS FOR 30-DAY PERIODS IN CY 2017

Discipline	2017 Average costs per visit (without NRS)	2017 Average number of visits	2017 30-day period costs (without NRS)	2017 Average NRS costs per visit	2017 Average Cost+NRS per visit	2017 30-day period costs with NRS
Skilled Nursing	$135.93	4.88	$663.34	$3.58	$139.51	$680.81
Physical Therapy	$156.59	3.45	$540.24	$3.58	$160.17	$552.59
Occupational Therapy	$153.13	1.03	$157.72	$3.58	$156.71	$161.41
Speech Pathology	$169.89	0.21	$35.68	$3.58	$173.47	$36.43
Medical Social Services	$223.96	0.08	$17.92	$3.58	$227.54	$18.20
Home Health Aides	$61.83	0.86	$53.17	$3.58	$65.41	$56.25
Total		10.50	**$1,468.07**			**$1,505.69**

Source: Medicare cost reports were pulled in January 2019. Medicare claims data from 2017 was pulled from the CCW in August 2018. The 30-day periods were simulated from 60-day episodes and excluded low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes. The 30-day periods were linked to OASIS assessments and covered the 60-day episodes ending in CY 2017.

To estimate the costs for CY 2020, we updated the estimated 30-day period costs with NRS by the home health market basket update, minus the multifactor productivity adjustment for CYs 2018 and 2019. For CY 2020, the BBA of 2018 requires a market basket update of 1.5 percent. The estimated costs for 30-day periods by discipline and the total estimated cost for a 30-day period for CY 2020 is shown in Table 5.

TABLE 5: ESTIMATED COSTS FOR 30-DAY PERIODS IN CY 2020

Discipline	2017 30-day Period Costs with NRS	2018 Market Basket (statutory)	2019 Market Basket Update minus MFP	2020 Market Basket Update (statutory)	CY 2020 Estimated 30-Day Costs with NRS
Skilled Nursing	$680.81	1.01	1.022	1.015	$713.29
Physical Therapy	$552.59	1.01	1.022	1.015	$578.95
Occupational Therapy	$161.41	1.01	1.022	1.015	$169.11
Speech Pathology	$36.43	1.01	1.022	1.015	$38.17
Medical Social Services	$18.20	1.01	1.022	1.015	$19.07
Home Health Aides	$56.25	1.01	1.022	1.015	$58.93
Total	**$1,505.69**	1.01	1.022	1.015	**$1,577.52**

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The estimated, budget-neutral 30-day payment for CY 2020 is $1,754.37 as described in section III.E. of this proposed rule. Updating this amount by the CY 2020 home health market basket of 1.5 percent and the wage index budget neutrality factor results in an estimated CY 2020 30-day payment amount of $ $1,791.73, approximately 14 percent more than the estimated CY 2020 30-day period cost of $1,577.52. After implementation of the 30-day unit of payment and the PDGM in CY 2020, we will continue to analyze the costs by discipline as well as the overall cost for a 30-day period of care to determine the effects, if any, of these changes.

III. Proposed Provisions for Payment Under the Home Health Prospective Payment System (HH PPS)

A. Implementation of the Patient-Driven Groupings Model (PDGM) for CY 2020

1. Background and Legislative History

In the CY 2019 HH PPS final rule (83 FR 56406), we finalized provisions to implement changes mandated by the BBA of 2018 for CY 2020, which included a change in the unit of payment from a 60-day episode of care to a 30-day period of care, as required by section 51001(a)(1)(B), and the elimination of therapy thresholds used for adjusting home health payment, as required by section 51001(a)(3)(B). In order to eliminate the use of therapy thresholds in adjusting payment under the HH PPS, we finalized an alternative case mix-adjustment methodology, known as the Patient-Driven Groupings Model (PDGM), to be implemented for home health periods of care beginning on or after January 1, 2020.

In regard to the 30-day unit of payment, section 51001(a)(1) of the BBA of 2018 amended section 1895(b)(2) of the Act by adding a new subparagraph (B) to require the Secretary to apply a 30-day unit of service, effective January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service furnished that start and end during the 12-month period beginning January 1, 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 service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Section 1895(b)(3)(A)(iv) of the Act additionally requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS described these behavior assumptions in the CY 2019 HH PPS proposed rule (83 FR 32389) and these assumptions are further described in section III.F. of this proposed rule.

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases, based on retrospective behavior, to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. And finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

2. Overview and CY 2020 Implementation of the PDGM

To better align payment with patient care needs and better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule (83 FR 56406), we finalized case-mix methodology refinements through the PDGM for home health periods of care beginning on or after January 1, 2020. We believe that the PDGM case-mix methodology better aligns payment with patient care needs and is a patient-centered model that groups periods of care in a manner consistent with how clinicians differentiate between patients and the primary reason for needing home health care. This proposed rule would set forth the requirements for the implementation of the PDGM, as well as updates to the PDGM case-mix weights and payment rates, which would be effective on January 1, 2020. The PDGM and a change to a 30-day unit of payment were finalized in the CY 2019 HH PPS final rule (83 FR 56406) and, as such, there are no new policy proposals in this proposed rule on the structure of the PDGM or the change to a 30-day unit of payment. However, there are proposals related to the split-percentage payments upon implementation of the PDGM and the 30-day unit of payment in section III.G. of this proposed rule.

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. A national, standardized 30-day period payment amount, as described in section III.F. of this proposed rule, would be adjusted by the case-mix weights as determined by the variables in the PDGM. Payment for non-routine supplies (NRS) is now included in the national, standardized 30-day payment amount. In total, there are 432 different payment groups in the PDGM. These 432 Home Health Resource Groups (HHRGs) represent the different payment groups based on five main case-mix variables under the PDGM, as shown in Diagram B1, and subsequently described in more detail throughout this section.

Under this new case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories listed in this section of this proposed rule (timing, admission source, clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. Annually recalibrating the PDGM case-mix weights ensures that the case-mix weights reflect the most recent utilization data at the time of annual rulemaking. The proposed CY 2020 PDGM case-mix weights are listed in section III.D. of this proposed rule.

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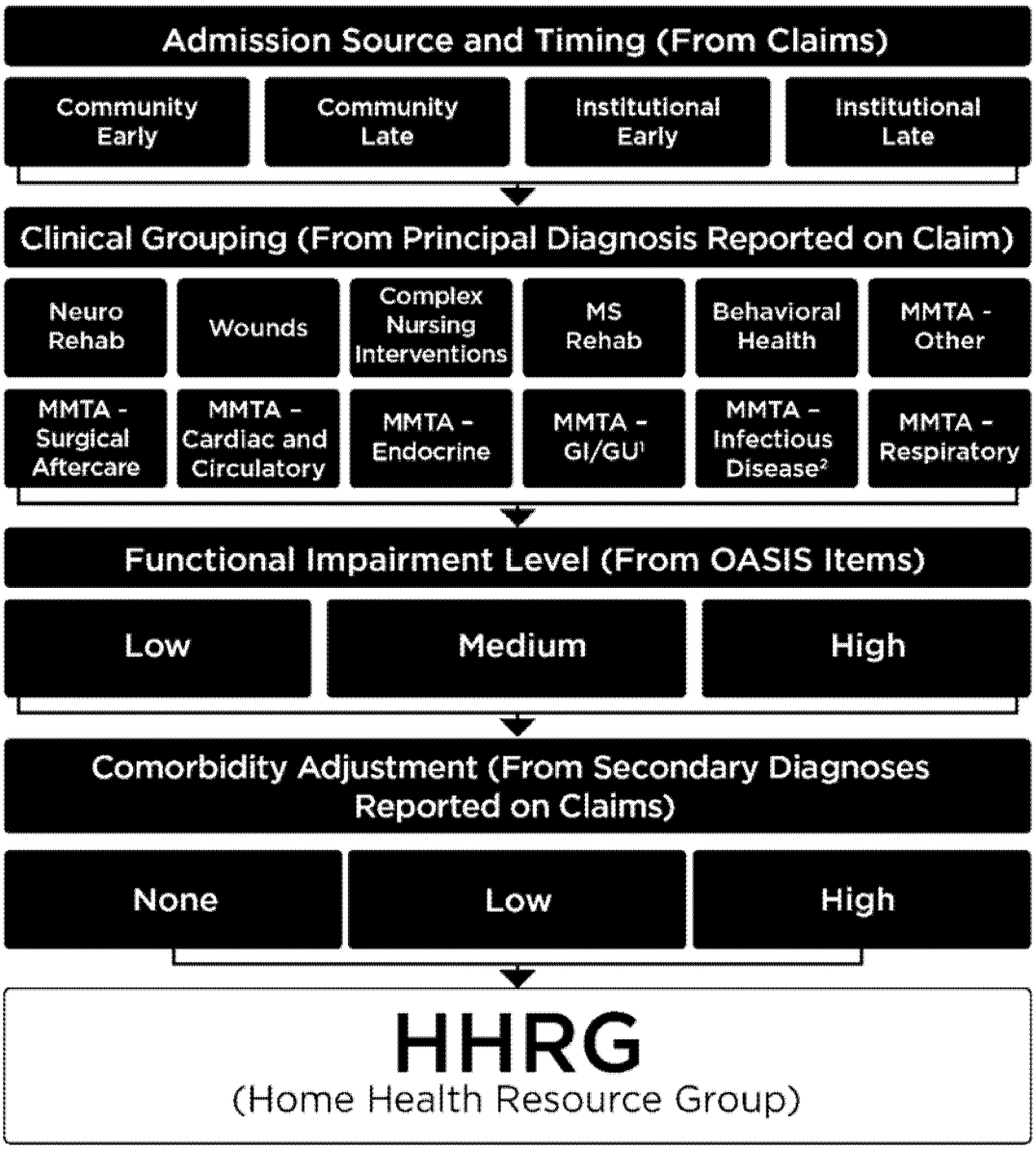
FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



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a. Timing

Under the PDGM, 30-day periods of care will be classified as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods. Under the PDGM, the first 30-day period of care will be classified as early and all subsequent 30-day periods of care in the sequence (second or later) will be classified as late. A 30-day period will not be considered early unless there is a gap of more than 60 days between the end of one period of care and the start of another. Information regarding the timing of a 30-day period of care will come from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is ''early'' or ''late''. While the PDGM case-mix adjustment is applied to each 30-day period of care, other home health requirements will continue on a 60-day basis. Specifically, certifications and recertifications continue on a 60-day basis and the comprehensive assessment will 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.''

b. Admission Source

Each 30-day period of care will 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. Thirty-day periods of care 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 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, meaning SNF, IRF, LTCH, or IPF stays, that occur during a previous 30-day period of care and within 14 days of a subsequent, contiguous 30-day period of care as institutional (that is, the ''admission date'' and ''from date'' for the subsequent 30-day period of care do not match), 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. All other 30-day periods of care would be designated as community admissions.

Information from the Medicare claims processing system will determine the appropriate admission source for final claim payment. The OASIS assessment will not be utilized in evaluating for admission source information. We believe that obtaining this information from the Medicare claims processing system, rather than as reported on the OASIS, is a more accurate way to determine admission source information as HHAs may be unaware of an acute or post-acute care stay prior to home health admission. While HHAs can report an occurrence code on submitted claims to indicate the admission source, obtaining this information from the Medicare claims processing system allows CMS the opportunity and flexibility to verify the source of the admission and correct any improper payments as deemed appropriate. When the Medicare claims processing system receives a Medicare home health claim, the systems will check for the presence of a Medicare acute or post-acute care claim for an institutional stay. If such an institutional claim is found, and the institutional claim occurred within 14 days of the home health admission, our systems will trigger an automatic adjustment to the corresponding HH claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or post-acute care claim for an institutional stay, the systems will check for the presence of a HH claim with a community admission source payment group. If such HH claim is found, and the institutional stay occurred within 14 days prior to 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.

However, situations in which the HHA has information about the acute or post-acute care stay, HHAs will be allowed to manually indicate on Medicare home health claims that an institutional admission source had occurred prior to the processing of an acute/post-acute Medicare claim, in order to receive higher payment associated with the institutional admission source. This will be done through the reporting of one of two admission source occurrence codes on home health claims—

- Occurrence Code 61: To indicate an acute care hospital discharge within 14 days prior to the ''From Date'' of any home health claim; or
- Occurrence Code 62: To indicate a SNF, IRF, LTCH, or IPF discharge with 14 days prior to the ''Admission Date'' of the first home health claim.

If the HHA does not include an occurrence code on the HH claim to indicate that that the home health patient had a previous acute or post-acute care stay, the period of care will be categorized as a community admission source. However, if later a Medicare acute or post-acute care 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 will be automatically adjusted as an institutional admission and the appropriate payment modifications will be made. For purposes of a Request for Anticipated Payment (RAP), only the final claim will be adjusted to reflect the admission source. More information regarding the admission source reporting requirements for RAP and claims submission can be found in Change Request 11081, ''Home Health (HH) Patient-Drive Groupings Model (PDGM)-Split Implementation''.[1] Accordingly, the Medicare Claims Processing Manual, chapter 10,[2] will be updated to reflect all of the claims processing changes associated with implementation of the PDGM.

c. Clinical Groupings

Each 30-day period of care will be grouped into one of 12 clinical groups which describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on home health claims. The 12 clinical groups are listed and described in Table 6.

[1] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4244CP.pdf.*

[2] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf.*

TABLE 6: PDGM CLINICAL GROUPS

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 and substance abuse 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

It is possible for the principal diagnosis to change between the first and second 30-day period of care and the claim for the second 30-day period of care would reflect the new principal diagnosis. HHAs would not change the claim for the first 30-day period. However, a change in the principal diagnosis does not necessarily mean that an ''other follow-up'' OASIS assessment (RFA 05) would need to be completed just to make the diagnoses match. However, if a patient experienced a significant change in condition before the start of a subsequent, contiguous 30-day period of care, for example due to a fall, in accordance with § 484.55(d)(1)(ii) the HHA is required to update the comprehensive assessment. The Home Health Agency Interpretive Guidelines for § 484.55(d), state that a marked improvement or worsening of a patient's condition, which changes, and was not anticipated in, the patient's plan of care would be considered a ''major decline or improvement in the patient's health status'' that would warrant update and revision of the comprehensive assessment.[3] Additionally, in accordance with § 484.60, the total plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date.

In the event of a significant change of condition warranting an updated comprehensive assessment, an ''other follow-up assessment'' (RFA 05) would be submitted before the start of a subsequent, contiguous 30-day period, which may reflect a change in the functional impairment level and the second 30-day claim would be grouped into its appropriate case-mix group accordingly. An ''other follow-up assessment'' is a comprehensive assessment conducted due to a major decline or improvement in patient's health status occurring at a time other than during the last 5 days of the episode. This assessment is done to re-evaluate the patient's condition, allowing revision to the patient's care plan as appropriate. The ''Outcome and Assessment Information Set OASIS–D Guidance Manual,'' effective January 1, 2019, provides more detailed guidance for the completion of an ''other follow-up'' assessment.[4] In this respect, two 30-day periods can have two different case-mix groups to reflect any changes in patient condition. 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 an adjustment to the original claim submitted if an assessment was completed before the start of the second 30-day period, but was received after the claim was submitted and if the assessment items would change the payment grouping.

HHAs would determine whether or not to complete a follow-up OASIS assessment for a second 30-day period of care depending on the individual's clinical circumstances. For example, if the only change from the first 30-day period and the second 30-day period is a change to the principal diagnosis and there is no change in the patient's function, the HHA may determine it is not necessary to complete a follow-up assessment. Therefore, the expectation is that HHAs would determine whether an ''other follow-up'' assessment is required based on the individual's overall condition, the effects of the change on the overall home health plan of care, and in accordance with the home health CoPs, interpretive guidelines, and the OASIS D Guidance Manual instructions, as previously noted.

For case-mix adjustment purposes, the principal diagnosis reported on the home health claim will determine the clinical group for each 30-day period of care. Currently, billing instructions state that the principal diagnosis on the OASIS must also be the principal diagnosis on the final claim; however, we will update our billing instructions to clarify that there will be no need for the HHA to complete an ''other follow-up'' assessment (an RFA 05) just to make the diagnoses match. Therefore, for claim ''From'' dates on or after January 1, 2020, the ICD–10–CM code and principal diagnosis used for payment grouping will be from the claim rather than the OASIS. As a result, the claim and OASIS diagnosis codes will no longer be expected to match in all cases. Additional claims processing guidance, including the role of the OASIS item set will be included

[3] State Operations Manual (SOM), Appendix B. *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-25-HHA.pdf.*

[4] Outcome and Assessment Information Set OASIS–D Guidance Manual Effective January 1, 2019 available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D-Guidance-Manual-final.pdf.*

in the Medicare Claims Processing Manual, chapter 10.[5]

While these clinical groups represent the primary reason for home health services during a 30-day period of care, this does not mean that they represent the only reason for home health services. While there are clinical groups where the primary reason for home health services is for therapy (for example, Musculoskeletal Rehabilitation) and other clinical groups where the primary reason for home health services is for nursing (for example, Complex Nursing Interventions), home health remains a multidisciplinary benefit and payment is bundled to cover all necessary home health services identified on the individualized home health plan of care. Therefore, regardless of the clinical group assignment, HHAs are required, in accordance with the home health CoPs at § 484.60(a)(2), to ensure that the individualized home health plan of care addresses all care needs, including the disciplines to provide such care. Under the PDGM, the clinical group is just one variable in the overall case-mix adjustment for a home health period of care.

Finally, we note that we will update the Interactive Grouper Tool posted on both the HHA Center web page (*https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html*) and the dedicated PDGM web page (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html*). This Interactive Grouper Tool will include all of the ICD–10 diagnosis codes used in the PDGM and may be used by HHAs to generate PDGM case-mix weights for their patient census. This tool is for informational and illustrative purposes only. HHAs can also request a Home Health Claims-OASIS Limited Data Set (LDS) to accompany the CY 2020 HH PPS proposed and final rules to support HHAs in evaluating the effects of the PDGM. 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.*

d. Functional Impairment Level

Under the PDGM, each 30-day period of care will be placed into one of three functional impairment levels, low, medium, or high, based on responses to certain OASIS functional items as listed in Table 7.

TABLE 7: OASIS ITEMS USED FOR FUNCTIONAL IMPAIRMENT LEVEL IN THE PDGM

OASIS Item	Description
M1033	Risk for Hospitalization*
M1800	Grooming
M1810	Current ability to dress upper body safely
M1820	Current ability to dress lower body safely
M1830	Bathing
M1840	Toilet transferring
M1850	Transferring
M1860	Ambulation and locomotion

*Excluding responses 8, 9, and 10

Responses to these OASIS items are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, ''Overview of the Home Health Groupings Model'' posted on the Home Health Center web page.[6] The sum of these points' results in a functional impairment level score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. For CY 2020, we used CY 2018 claims data to update the functional points and functional impairment levels by clinical group. The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2020 are listed in Tables 4 and 5, respectively. For ease of use, instead of listing the response categories and the associated points (as shown in Table 28 in the CY 2019 HH PPS final rule, 83 FR 56478), we have reformatted the OASIS Functional Item Response Points (Table 8) to identify how the OASIS functional items used for the functional impairment level are assigned points under the PDGM. In the CY 2020 HH PPS final rule, we will update the points for the OASIS functional item response categories and the functional impairment levels by clinical group using the most recent, available claims data.

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[5] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf.*

[6] *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

TABLE 8: CY 2020 OASIS POINTS FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS

	Responses	Points (2018)	Percent of Periods in 2018 with this Response Category
M1800: Grooming	0 or 1	0	39.6%
	2 or 3	5	60.4%
M1810: Current Ability to Dress Upper Body	0 or 1	0	37.5%
	2 or 3	6	62.5%
M1820: Current Ability to Dress Lower Body	0 or 1	0	18.1%
	2	6	60.5%
	3	12	21.4%
M1830: Bathing	0 or 1	0	4.6%
	2	3	16.6%
	3 or 4	12	54.0%
	5 or 6	20	24.9%
M1840: Toilet Transferring	0 or 1	0	66.3%
	2, 3 or 4	5	33.7%
M1850: Transferring	0	0	2.5%
	1	3	32.3%
	2, 3, 4 or 5	6	65.2%
M1860: Ambulation/Locomotion	0 or 1	0	6.2%
	2	9	22.6%
	3	11	55.9%
	4, 5 or 6	23	15.3%
M1032: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	81.2%
	Four or more items marked (Excluding responses 8, 9 or 10)	11	18.8%

Source: CY 2018 home health claims and OASIS data.

TABLE 9: CY 2020 THRESHOLDS FOR FUNCTIONAL IMPAIRMENT LEVELS BY CLINICAL GROUP

Clinical Group	Level of Impairment	Points (2018 Data)
MMTA - Other	Low	0-32
	Medium	33-49
	High	50+
Behavioral Health	Low	0-35
	Medium	36-52
	High	53+
Complex Nursing Interventions	Low	0-38
	Medium	39-57
	High	58+
Musculoskeletal Rehabilitation	Low	0-38
	Medium	39-51
	High	52+
Neuro Rehabilitation	Low	0-44

Clinical Group	Level of Impairment	Points (2018 Data)
	Medium	45-59
	High	60+
Wound	Low	0-41
	Medium	42-60
	High	61+
MMTA - Surgical Aftercare	Low	0-37
	Medium	38-51
	High	52+
MMTA - Cardiac and Circulatory	Low	0-35
	Medium	36-51
	High	52+
MMTA - Endocrine	Low	0-35
	Medium	36-51
	High	52+
MMTA - Gastrointestinal tract and Genitourinary System	Low	0-40
	Medium	41-54
	High	55+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-35
	Medium	36-51
	High	52+
MMTA - Respiratory	Low	0-37
	Medium	38-51
	High	52+

Source: CY 2018 home health claims and OASIS data.

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The functional impairment level will remain the same for the first and second 30-day periods of care unless there has been a significant change in condition which warranted an ''other follow-up'' assessment prior to the second 30-day period of care. For each 30-day period of care, the Medicare claims processing system will look for the most recent OASIS assessment based on the claims ''from date.'' The proposed CY 2020 functional points table and the functional impairment level thresholds table will be posted on the HHA Center web page at *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html* as well as on the dedicated PDGM web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html.*

e. Comorbidity Adjustment

Thirty-day periods will receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the diagnoses have at least as high as the median resource use and represent more that 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to if they were reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *No comorbidity adjustment:* A 30-day period of care will receive no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment.

In CY 2020, there are 12 low comorbidity adjustment subgroups as identified in Table 10 and 34 high comorbidity adjustment interaction subgroups as identified in Table 11. In the CY 2020 HH PPS final rule, we will update the comorbidity subgroups and interaction subgroups using the most recent, available claims data.

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TABLE 10: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2020

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 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 2018 Medicare claims data for episodes ending on or before December 31, 2018.

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TABLE 11: HIGH COMORBIDITY ADJUSTMENT INTERACTION SUBGROUPS FOR CY 2020

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 11	Includes heart failure
4	Cerebral 4	Includes sequelae of cerebral vascular diseases	Neuro 10	Includes peripheral and polyneuropathies
5	Circulatory 4	Includes hypertensive chronic kidney disease	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
6	Circulatory 4	Include hypertensive chronic kidney disease	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
7	Circulatory 4	Include hypertensive chronic kidney disease	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
8	Circulatory 7	Includes atherosclerosis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
9	Endocrine 3	Includes diabetes with complications	Neuro 5	Includes Parkinson's disease
10	Endocrine 3	Includes diabetes with complications	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia
11	Endocrine 3	Includes diabetes with complications	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
12	Endocrine 3	Includes diabetes with complications	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
13	Heart 10	Includes cardiac dysrhythmias	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
14	Heart 10	Includes cardiac dysrhythmias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
15	Heart 11	Includes heart failure	Neuro 10	Includes peripheral and polyneuropathies
16	Heart 11	Includes heart failure	Neuro 5	Includes Parkinson's disease
17	Heart 11	Includes heart failure	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
18	Heart 11	Includes heart failure	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
19	Heart 11	Includes heart failure	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
20	Heart 12	Includes other heart diseases	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
21	Heart 12	Includes other heart diseases	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
22	Neuro 10	Includes peripheral and polyneuropathies	Neuro 5	Includes Parkinson's disease
23	Neuro 10	Includes peripheral and polyneuropathies	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
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 2018 Medicare claims data for episodes ending on or before December 31, 2018.

A 30-day period of care can have 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 will be the same across the subgroups and the high comorbidity adjustment will be the same across the subgroup interactions. The proposed CY 2020 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will be posted on the HHA Center webpage at *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html* as well as on the dedicated PDGM web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html.*

B. Implementation of a 30-Day Unit of Payment for CY 2020

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. Section 1895(b)(3)(A)(iv) of the Act also requires that in calculating a 30-day payment amount in a budget-neutral manner to the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment. In addition, in calculating a 30-day payment amount in a budget-neutral manner, we must take into account behavior changes that could occur as a result of the case-mix adjustment factors that are implemented 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 the home health applicable percentage increase, the adjustment if quality data are not reported, and the productivity adjustment.

In the CY 2019 HH PPS proposed rule (83 FR 32389), 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:* A key component of determining payment under the PDGM is the 30-day period of care's clinical group assignment, which is based on the principal diagnosis code for the patient as reported by the HHA on the home health claim. Therefore, we proposed to assume that HHAs will change their documentation and coding practices and would put the highest paying diagnosis code as the principal diagnosis code in order to have a 30-day period of care be placed into a higher-paying clinical group. While we do not support or condone coding practices or the provision of services solely to maximize payment, we often take into account in proposed rules the potential behavior effects of policy changes should they be finalized and implemented.

- *Comorbidity Coding:* The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. While the OASIS only allows HHAs to designate 1 primary diagnosis and 5 secondary diagnoses, the home health claim allows HHAs to designate 1 principal diagnosis and 24 secondary diagnoses. Therefore, we proposed to assume that by taking into account additional ICD–10–CM diagnosis codes listed on the home health claim (that exceed the 6 allowed on the OASIS), 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. The comorbidity adjustment in the PDGM can increase payment by up to 20 percent.

- *LUPA Threshold:* Rather than being paid the per-visit amounts for a 30-day period of care subject to the low-utilization payment adjustment (LUPA) under the proposed PDGM, we proposed to assume 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.[7] LUPAs are paid when there are a low number of visits furnished in a 30-day period of care. Under the PDGM, the LUPA threshold ranges from 2–6 visits depending on the case-mix group assignment for a particular period of care (see section III.D. of this proposed rule for the LUPA thresholds that correspond to the 432 case-mix groups under the PDGM).

While some commenters supported these three behavior assumptions in calculating the budget-neutral 30-day payment amount, many commenters disagreed with these assumptions stating that they seem arbitrary, overly complex, and that they lack any foundation in evidence-based data. Other commenters expressed concern that the behavior assumptions would result in too high of a payment reduction and that this could create potential access issues. However, in the CY 2019 HH PPS final rule, we explained why we believe the three behavior assumptions are appropriate based on previously obtained data and precedent for adjusting home health prospective payments based on assumed behavior changes. We believe that our examples and past experiences described in more detail in the CY 2019 HH PPS final rule (83 FR 56456) demonstrate that there is a substantive connection between the data and the behavior assumptions made. Furthermore, the Medicare Payment Advisory Commission (MedPAC) provided comments on the CY 2019 HH PPS proposed rule and expressed their support for the behavior assumptions, stating that past experience with the home health PPS demonstrates that HHAs have changed coding, utilization, and the mix of services provided in reaction to new payment incentives. Similarly, in its March, 2019 Report to Congress, MedPAC stated that behavior assumptions are necessary to offset the spending increase expected in 2020 resulting from the behavior changes.[8]

With regards to our assumption that HHAs would code the highest-paying diagnosis code as primary for the clinical grouping assignment, this assumption is based on decades of past experience under the case-mix system for the HH PPS and other case-mix systems. For example, we summarized previous data regarding the substantial increase in payments when transitioning from the diagnosis-related groups (DRGs) to the Medicare Severity (MS)-DRGs that were not related to actual changes in patient severity. Subsequent analysis of inpatient hospital claims data supported prospective payment adjustments to account for documentation and coding effects was detailed in both the FY 2010 and FY 2011 IPPS final rules (74 FR 43770 and 75 FR 50356). We also noted

[7] Current data suggest that what would be about ⅓ of the LUPA episodes with visits near the LUPA threshold move up to become non-LUPA episodes. We assume this experience will continue under the PDGM, with about ⅓ of those episodes 1 or 2 visits below the thresholds moving up to become non-LUPA episodes.

[8] MedPAC Report to Congress, Home Care Services, chapter 9, March, 2019. *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch9_sec.pdf?sfvrsn=0.*

that in the first year of the Inpatient Rehabilitation Facility (IRF) PPS, there were instances where case-mix increases resulted from documentation and coding-induced changes (72 FR 47181). Similarly, we cited multiple instances where CMS analyzed the 2008 case-mix methodology refinements that resulted in the 153-group HH PPS case-mix model to measure change in case-mix, both real and nominal (74 FR 40958 and 75 FR 43238). We stated that our analysis subsequent to these refinements to the current case-mix methodology show an average of approximately 2 percent nominal case-mix growth per year (82 FR 35274).

For the comorbidity coding assumption, we stated that using the home health claim for the comorbidity adjustment as opposed to the OASIS provides more opportunity to report all comorbid conditions that may affect the plan of care. The OASIS item set only allows HHAs to report up to five secondary diagnoses, while the home health claim (837I institutional claim format-electronic version of the UB–04) allows HHAs to report up to 24 secondary diagnoses. Furthermore, ICD–10 coding guidelines require reporting of all secondary (additional) diagnoses that affect the plan of care. Because the comorbidity adjustment can increase payment by up to 20 percent, it is a reasonable assumption that HHAs would encourage the accurate reporting of secondary diagnoses affecting the home health plan of care to more accurately identify the conditions affecting resource use.

Finally, regarding the LUPA threshold assumption, in the CY 2019 HH PPS final rule, we referenced data from the FY 2001 HH PPS final rule where the episode file showed that approximately 16 percent of episodes would have received a LUPA (meaning the 60-day episode had 4 or fewer visits). We also stated that currently only about 7 percent of all 60-day episodes receive a LUPA, meaning that it appears that HHAs changed their practice patterns such that, upon implementation of the HH PPS, more than half of 60-day episodes that would have been LUPAs received the full 60-day episode payment amount. Additionally, while the LUPA thresholds vary for each of the 432 case-mix groups, many of these groups have a LUPA threshold of two, meaning if the HHA provides more than one visit in a 30-day period, it will receive the full 30-day payment amount. Given that many groups have only a two-visit threshold, we believe it to be a reasonable assumption that some HHAs would provide a second visit to receive the full 30-day payment amount. In the CY 2019 HH PPS final rule, we finalized the three behavior assumptions in calculating a 30-day budget-neutral payment amount given the ample evidence-based data supporting such assumptions (83 FR 56461). In response to comments regarding the impact of the behavior assumptions on payments and any potential access issues, in the CY 2019 HH PPS final rule (83 FR 56461), we stated that we expect that HHAs would continue to provide home health services in accordance with the home health Conditions of Participation regarding the provision of services as established on the individualized home health plan of care. We stated that we expect the provision of services to be made to best meet the patient's care needs. We also noted that we would monitor any changes in utilization patterns, beneficiary impact, and provider behavior to see if any refinements to the PDGM would be warranted, or if any concerns are identified that may signal the need for appropriate program integrity measures.

In order to calculate the CY 2020 proposed budget neutral 30-day payment amounts in this proposed rule, both with and without behavior assumptions, we first calculated the total, aggregate amount of expenditures that would occur under the current case-mix adjustment methodology (as described in section III.D. of this rule) and the 60-day episode unit of payment using the CY 2019 payment parameters (for example, CY 2019 payment rates, case-mix weights, and outlier fixed-dollar loss ratio). That resulted in a total aggregate expenditures target amount of $16.2 billion.[9] We then calculated what the 30-day payment amount would need to be set at in CY 2020, with and without behavior assumptions, while taking into account needed changes to the outlier fixed-dollar loss ratio under the PDGM in order to pay out no more than 2.5 percent of total HH PPS payments as outlier payments (refer to section III.F. of this proposed rule) and in order for Medicare to pay out $16.2 billion in total expenditures in CY 2020 with the application of a 30-day unit of payment under the PDGM. Table 12 includes the proposed, estimated 30-day budget-neutral payment amount for CY 2020 both with and without the behavior assumptions. These payment amounts do not include the CY 2020 home health payment update of 1.5 percent.

[9] The initial 2018 analytic file included 6,606,602 60-day episodes ($18.3 billion in total expenditures). Of these, 962,949 (14.6 percent) were excluded because they could not be linked to OASIS assessments or because of the claims data cleaning process reasons listed in section III.F.1 of this proposed rule. We note that of the 962,949 claims excluded, 513,998 were excluded because they were RAPs without a final claim or they were claims with zero payment amounts, resulting in $17.4 billion in total expenditures. After removing all 962,949 excluded claims, the 2018 analytic file consisted of 5,643,653 60-day episodes ($16.3 billion in total expenditures). 60-day episodes of duration longer than 30 days were divided into two 30-day periods in order to calculate the 30-day payment amounts. As noted in section III.F.1. of this proposed rule, there were instances where 30-day periods were excluded from the 2018 analytic file (for example, we could not match the period to a start of care or resumption of care OASIS to determine the functional level under the PDGM, the 30-day period did not have any skilled visits, or because information necessary to calculate payment was missing from claim record). The final 2018 analytic file used to calculate budget neutrality consisted of 9,127,459 30-day periods ($16.2 billion in total expenditures) drawn from 5,338,939 60-day episodes.

TABLE 12: CY 2020 PROPOSED, ESTIMATED 30-DAY BUDGET-NEUTRAL PAYMENT AMOUNTS

Behavior Assumption	30-day Budget Neutral (BN) Standard Amount	Percent Change from No Behavior Assumptions [1]	FDL Ratio
No Behavior Assumptions	$1,907.11		0.56
LUPA Threshold (1/3 of LUPAs 1-2 visits away from threshold get extra visits and become case-mix adjusted)	$1,871.67	-1.86%	0.59
Clinical Group Coding [2] (among available diagnoses, one leading to highest payment clinical grouping classification designated as principal)	$1,794.42	-5.91%	0.60
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	$1,900.05	-0.37%	0.56
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	$1,754.37	-8.01%	0.63

Notes:

[1] Adding all the percent decreases for each behavior assumption results in a total percent decrease of -8.14 percent. However, there is overlap and interactions between the behavior assumptions and when combined, the budget-neutral payment amount results in a -8.01 percent decrease from the payment amount without these assumptions applied.

[2] The clinical group coding assumption has a higher percent decrease (-5.91 percent) in this year's proposed rule compared to the percent decrease in the CY 2019 HH PPS proposed rule (-4.28 percent). This is because the CY 2019 clinical coding assumption was based on the six proposed clinical groups and the CY 2020 clinical coding assumption is based on the finalized 12 clinical groups.

If no behavior assumptions were made, we estimate that the CY 2020 30-day payment amount needed to achieve budget neutrality would be $1,907.11. Applying the clinical group and comorbidity coding assumptions, and the LUPA threshold assumption, as required by section 1895(b)(3)(A)(iv) of the Act, will result in the need to decrease the CY 2020 estimated budget-neutral 30-day payment amount to $1,754.37 (a 8.01 percent decrease from $1,907.11). The CY 2020 estimated 30-day budget-neutral payment amount would be slightly more than the CY 2019 estimated 30-day budget-neutral payment amount calculated in last year's rule (that is, if the PDGM was implemented in CY 2019), which we estimated to be $1,753.68. However, the CY 2019 estimated 30-day payment amount of $1,753.68 included the CY 2019 market basket update of 2.1 percent whereas the CY 2020 estimated 30-day budget neutral payment amount of $1,754.37 does not include the 1.5 percent home health legislated payment update for CY 2020. Applying the proposed CY 2020 Wage Index Budget Neutrality Factor and the 1.5 percent home health update would increase the CY 2020 national, standardized 30-day payment amount to $1,791.73 and is further described in section III.E. of this proposed rule. The CY 2020 proposed estimated payment rate of $1,791.73 is approximately 14 percent more than the estimated CY 2020 30-day period cost of $1,577.52, as shown in Table 5 of this proposed rule. We invite comments on the CY 2020 proposed, estimated 30-day budget-neutral payment amount with the behavior assumptions as described previously in this proposed rule and in Table 12.

The 30-day payment amount will be for 30-day periods of care beginning on and after January 1, 2020. Because CY 2020 is the first year of the PDGM and the change to a 30-day unit of payment, there will be a transition period to account for those home health episodes of care that span the implementation date. Therefore, for 60-day episodes (that is, not LUPA 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 will be the CY 2020 national, standardized 60-day episode payment amount as described in section III.X. of this proposed rule. For home health periods of care that begin on or after January 1, 2020, the unit of service will be a 30-day period and payment made under the Medicare HH PPS will be the CY 2020 national, standardized prospective 30-day payment amount as described in section III.X. of this proposed rule. For home health units of service that begin on or after December 3, 2020 through December 31, 2020 and end on or after January 1, 2021, the HHA will be paid the CY 2021 national, standardized prospective 30-day payment amount.

We note 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. The data from CYs 2020 through 2026 will be available to determine whether a prospective adjustment (increase or decrease) is needed no earlier than in years 2022 through 2028 rulemaking. However, we will analyze data after implementation of the PDGM to determine if there are any notable and consistent trends to warrant whether any changes to the national, standardized 30-day payment rate should be done earlier than CY 2022.

As noted previously, under section 1895(b)(3)(D)(ii) of the Act, we are required to provide one or more permanent adjustments to the 30-day payment amount on a prospective basis, if needed, to offset increases or decreases in estimated aggregate expenditures as calculated under section 1895(b)(3)(D)(i) of the Act. Clause (iii) of section 1895(b)(3)(D) of the Act requires the Secretary to make temporary adjustments to the 30-day payment amount, on a prospective basis, in order to offset increases or decreases in estimated aggregate expenditures, as determined under clause (i) of such section. The temporary adjustments allow us to recover excess spending or give back the difference between actual and estimated spending (if actual is less than estimated) not addressed by permanent adjustments.

However, any permanent or temporary adjustments to the 30-day payment amount to offset increases or decreases in estimated aggregate expenditures as calculated under section 1895(b)(3)(D)(i) and (iii) of the Act would be subject to proposed notice and comment rulemaking.

We are soliciting comments on the behavior assumptions finalized in the CY 2019 HH PPS final rule regarding any potential issues that may result from taking these assumptions into account when establishing the initial 30-day payment amount for CY 2020. We reiterate that if CMS underestimates the reductions to the 30-day payment amount necessary to offset behavior changes and maintain budget neutrality, larger adjustments to the 30-day payment amount would be required in the future, by law, to ensure budget neutrality. Likewise, if CMS overestimates the reductions, we are required to make the appropriate payment adjustments accordingly as described previously.

We wish to remind stakeholders again that CMS will provide, upon request, a Home Health Claims-OASIS LDS file to accompany the CY 2020 proposed and final rules to support HHAs in evaluating the effects of the PDGM. 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.* Additionally, we will post CY 2020 provider-level impacts and an updated Interactive Grouper Tool on the HHA Center web page [10] and the PDGM dedicated web page [11] to provide HHAs with ample tools to help them understand the impact of the PDGM and the change to a 30-day unit of payment.

C. Proposed CY 2020 HH PPS Case-Mix Weights for 60-Day Episodes of Care That Span the Implementation Date of the PDGM

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. 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. In this proposed rule, we are detailing implementation of the PDGM and a change in the unit of home health payment to 30-day periods of care as described in section III.A and III.B. of this proposed rule. As such, we are recalibrating the CY 2020 case-mix weights for 30-day periods of care using the PDGM methodology as described in section III.D. of the proposed rule. However, these recalibrated case-mix weights are not applicable for those 60-day episodes of care that begin on or before December 31, 2019 and end on or after January 1, 2020. Therefore, we are not proposing to separately recalibrate the case-mix weights for those 60-day episodes that span the January 1, 2020 implementation date.

Instead, we are proposing that these 60-day episodes would be paid the national, standardized 60-day episode payment amount as described in section III.E. of this rule and will be case-mix adjusted using the CY 2019 case-mix weights as listed in Table 6 in the CY 2019 HH PPS final rule (83 FR 56422) and posted on the HHA Center web page.[12] We believe that this is a reasonable approach for case-mix adjusting these 60-day episodes of care that span the January 1, 2020 implementation date. With the implementation of a new case-mix adjustment methodology and a move to a 30-day unit of payment, we believe this approach would be less burdensome for HHAs as they will not have to download a new, separate 153-group case-mix weight data file, in addition to the 432 case-mix weight data file for CY 2020. For those 60-day episodes that end after January 1, 2020, but where there is a continued need for home health services, we are proposing that any subsequent periods of care would be paid the 30-day national, standardized payment amount with the appropriate CY 2020 PDGM case-mix weight applied. We are soliciting comments on this proposal regarding payment for those 60-day episodes of care that span the implementation date of the PDGM and the change to a 30-day unit of payment.

D. Proposed CY 2020 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

1. Proposed CY 2020 PDGM LUPA Thresholds

Under the current 153-group payment system, 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). In the current payment system, approximately 7 to 8 percent of episodes are LUPAs.

LUPAs will still be paid upon implementation of the PDGM. However, the approach to calculating the LUPA thresholds has changed due to the change in the unit of payment to 30-day periods of care from 60-day episodes. As detailed in the CY 2019 HH PPS proposed rule (83 FR 32411), there are substantially more home health periods of care with four or fewer visits in a 30-day period than in 60-day episodes; therefore, we believe that the LUPA thresholds for 30-day periods of care should be correspondingly adjusted to target approximately the same percentage of LUPA episodes as under the current HH PPS case-mix system, which is approximately 7 to 8 percent of all episodes. To target approximately the same percentage of LUPAs under the PDGM, LUPA thresholds are set at the 10th percentile value of visits or 2 visits, whichever is higher, for each payment group. This means that the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. In the CY 2019 HH PPS final rule (83 FR 56492), we finalized that the LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available at the time of rulemaking. Therefore, we used CY 2018 Medicare home health claims (as of March 27, 2019) linked to OASIS assessment data for this proposed rule. The proposed LUPA thresholds for the CY 2020 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table 8. Under the PDGM, if the LUPA threshold is met, the 30-day period of care will be paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, as detailed previously, then payment will be made using the CY 2020 per-visit payment amounts. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or less visits, payment is made using the per-visit payment amounts.

[10] *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html.*

[11] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html.*

[12] *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html.*

2. Proposed CY 2020 PDGM Case-Mix Weights

Section 1895(b)(4)(B) of the Act 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. As finalized in the CY 2019 HH PPS final rule (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient characteristics (principal diagnosis, functional level, comorbid conditions, referral source and timing). The PDGM case-mix methodology results in 432 unique case-mix groups called HHRGs.

To generate the CY 2020 PDGM case-mix weights, we utilized a data file based on home health 30-day periods of care, as reported in CY 2018 Medicare home health claims (as of March 2019) linked to OASIS assessment data to obtain patient characteristics. These data are the most current and complete data available at this time. The claims data provides visit-level data and data on whether NRS was provided during the period and the total charges of NRS. We determine the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model as described in the steps detailed in this section of this proposed rule.

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM which are obtained from certain OASIS items. We measure resource use with the cost-per-minute + NRS approach that uses information from home health cost reports. Other variables in the regression model include the 30-day period's admission source; clinical group; and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium or high functional impairment level. We set those thresholds so that we assign roughly a third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

Step 2: Next, a second regression model estimates the relationship between a 30-day period's resource use and indicator variables for the presence of any of the comorbidities and comorbidity interactions that were originally examined for inclusion in the PDGM. Like the first regression model, this model also includes home health agency level fixed effects and includes control variables for each 30-day period's admission source, clinical group, timing, and functional impairment level. After we estimate the model, we assign comorbidities to the low comorbidity adjustment if any comorbidities have a coefficient that is statistically significant (p-value of .05 or less) and which have a coefficient that is larger than the 50th percentile of positive and statistically significant comorbidity coefficients. If two comorbidities in the model and their interaction term have coefficients that sum together to exceed $150 and the interaction term is statistically significant (p-value of .05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: After Step 2, each 30-day period is assigned to a clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. For each combination of those variables (which represent the 432 different payment groups that comprise the PDGM), we then calculate the 10th percentile of visits across all 30-day periods within a particular payment group. If a 30-day period's number of visits is less than the 10th percentile for their payment group, the 30-day period is classified as a Low Utilization Payment Adjustment (LUPA). If a payment group has a 10th percentile of visits that is less than two, we set the LUPA threshold for that payment group to be equal to two. That means if a 30-day period has one visit, it is classified as a LUPA and if it has two or more visits, it is not classified as a LUPA.

Step 4: Finally, we take all non-LUPA 30-day periods and regress resource use on the 30-day period's clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. The regression includes fixed effects at the level of the home health agency. After we estimate the model, the model coefficients are used to predict each 30-day period's resource use. To create the case-mix weight for each 30-day period, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression.

The case-mix weight is then used to adjust the base payment rate to determine each 30-day period's payment. Table 13 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

TABLE 13 – COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Coefficient Divided by Average Resource Use
MMTA - Other - Medium Functional	$224.06	0.1394
MMTA - Other - High Functional	$424.32	0.2639
MMTA - Surgical Aftercare - Low Functional	-$164.97	-0.1026
MMTA - Surgical Aftercare - Medium Functional	$97.62	0.0607
MMTA - Surgical Aftercare - High Functional	$352.85	0.2195
MMTA - Cardiac and Circulatory - Low Functional	-$28.23	-0.0176
MMTA - Cardiac and Circulatory - Medium Functional	$201.40	0.1253
MMTA - Cardiac and Circulatory - High Functional	$385.14	0.2396
MMTA - Endocrine - Low Functional	$185.56	0.1154
MMTA - Endocrine - Medium Functional	$445.53	0.2771
MMTA - Endocrine - High Functional	$614.49	0.3822
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$79.59	-0.0495
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$165.41	0.1029
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$304.62	0.1895
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$33.68	-0.0209
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$178.77	0.1112
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$356.17	0.2215
MMTA - Respiratory - Low Functional	-$65.41	-0.0407
MMTA - Respiratory - Medium Functional	$157.38	0.0979
MMTA - Respiratory - High Functional	$324.59	0.2019
Behavioral Health - Low Functional	-$123.88	-0.0771
Behavioral Health - Medium Functional	$142.04	0.0884
Behavioral Health - High Functional	$283.29	0.1762
Complex - Low Functional	-$75.97	-0.0473
Complex - Medium Functional	$238.65	0.1485
Complex - High Functional	$317.49	0.1975
MS Rehab - Low Functional	$126.23	0.0785
MS Rehab - Medium Functional	$297.36	0.1850
MS Rehab - High Functional	$540.40	0.3362
Neuro - Low Functional	$299.56	0.1863
Neuro - Medium Functional	$554.05	0.3446
Neuro - High Functional	$722.23	0.4493
Wound - Low Functional	$344.91	0.2145
Wound - Medium Functional	$591.71	0.3681
Wound - High Functional	$791.36	0.4923
Community - Late	-$659.24	-0.4101
Institutional - Early	$283.91	0.1766
Institutional - Late	$61.68	0.0384
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$96.49	0.0600
Comorbidity Adjustment - Has at least one interaction from interaction list	$304.67	0.1895
Constant	$1,617.59	
Average Resource Use	$1,607.62	
Number of 30-day Periods	8,456,330	
Adjusted R-Squared	0.3084	

Table 14 presents the HIPPS code, the LUPA threshold, and the case-mix weight for each Home Health Resource Group (HHRG) in the regression model.

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TABLE 14 – PROPOSED CY 2020 PDGM LUPA THRESHOLD AND CASE MIX WEIGHT FOR EACH HHRG PAYMENT GROUP

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)	CY 2020 Weights
1FC11	Behavioral Health - High	Early - Community	0	4	1.1824
1FC21	Behavioral Health - High	Early - Community	1	4	1.2424
1FC31	Behavioral Health - High	Early - Community	2	4	1.3719
2FC11	Behavioral Health - High	Early - Institutional	0	4	1.3590
2FC21	Behavioral Health - High	Early - Institutional	1	4	1.4190
2FC31	Behavioral Health - High	Early - Institutional	2	4	1.5485
3FC11	Behavioral Health - High	Late - Community	0	2	0.7723
3FC21	Behavioral Health - High	Late - Community	1	2	0.8324
3FC31	Behavioral Health - High	Late - Community	2	3	0.9619
4FC11	Behavioral Health - High	Late - Institutional	0	3	1.2208
4FC21	Behavioral Health - High	Late - Institutional	1	4	1.2808
4FC31	Behavioral Health - High	Late - Institutional	2	3	1.4103
1FA11	Behavioral Health - Low	Early - Community	0	3	0.9291
1FA21	Behavioral Health - Low	Early - Community	1	4	0.9892
1FA31	Behavioral Health - Low	Early - Community	2	3	1.1187
2FA11	Behavioral Health - Low	Early - Institutional	0	3	1.1058
2FA21	Behavioral Health - Low	Early - Institutional	1	3	1.1658
2FA31	Behavioral Health - Low	Early - Institutional	2	3	1.2953
3FA11	Behavioral Health - Low	Late - Community	0	2	0.5191
3FA21	Behavioral Health - Low	Late - Community	1	2	0.5791
3FA31	Behavioral Health - Low	Late - Community	2	2	0.7086
4FA11	Behavioral Health - Low	Late - Institutional	0	2	0.9675
4FA21	Behavioral Health - Low	Late - Institutional	1	2	1.0275
4FA31	Behavioral Health - Low	Late - Institutional	2	2	1.1570
1FB11	Behavioral Health - Medium	Early - Community	0	4	1.0946
1FB21	Behavioral Health - Medium	Early - Community	1	4	1.1546
1FB31	Behavioral Health - Medium	Early - Community	2	4	1.2841
2FB11	Behavioral Health - Medium	Early - Institutional	0	4	1.2712
2FB21	Behavioral Health - Medium	Early - Institutional	1	4	1.3312
2FB31	Behavioral Health - Medium	Early - Institutional	2	4	1.4607
3FB11	Behavioral Health - Medium	Late - Community	0	2	0.6845
3FB21	Behavioral Health - Medium	Late - Community	1	2	0.7445
3FB31	Behavioral Health - Medium	Late - Community	2	2	0.8740
4FB11	Behavioral Health - Medium	Late - Institutional	0	3	1.1329
4FB21	Behavioral Health - Medium	Late - Institutional	1	3	1.1930
4FB31	Behavioral Health - Medium	Late - Institutional	2	3	1.3224
1DC11	Complex - High	Early - Community	0	3	1.2037
1DC21	Complex - High	Early - Community	1	2	1.2637
1DC31	Complex - High	Early - Community	2	2	1.3932
2DC11	Complex - High	Early - Institutional	0	4	1.3803
2DC21	Complex - High	Early - Institutional	1	4	1.4403
2DC31	Complex - High	Early - Institutional	2	4	1.5698
3DC11	Complex - High	Late - Community	0	2	0.7936
3DC21	Complex - High	Late - Community	1	2	0.8536
3DC31	Complex - High	Late - Community	2	2	0.9831
4DC11	Complex - High	Late - Institutional	0	3	1.2421

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)	CY 2020 Weights
4DC21	Complex - High	Late - Institutional	1	3	1.3021
4DC31	Complex - High	Late - Institutional	2	3	1.4316
1DA11	Complex - Low	Early - Community	0	3	0.9589
1DA21	Complex - Low	Early - Community	1	3	1.0190
1DA31	Complex - Low	Early - Community	2	2	1.1485
2DA11	Complex - Low	Early - Institutional	0	3	1.1356
2DA21	Complex - Low	Early - Institutional	1	4	1.1956
2DA31	Complex - Low	Early - Institutional	2	4	1.3251
3DA11	Complex - Low	Late - Community	0	2	0.5489
3DA21	Complex - Low	Late - Community	1	2	0.6089
3DA31	Complex - Low	Late - Community	2	2	0.7384
4DA11	Complex - Low	Late - Institutional	0	2	0.9973
4DA21	Complex - Low	Late - Institutional	1	2	1.0573
4DA31	Complex - Low	Late - Institutional	2	2	1.1868
1DB11	Complex - Medium	Early - Community	0	3	1.1547
1DB21	Complex - Medium	Early - Community	1	3	1.2147
1DB31	Complex - Medium	Early - Community	2	3	1.3442
2DB11	Complex - Medium	Early - Institutional	0	4	1.3313
2DB21	Complex - Medium	Early - Institutional	1	4	1.3913
2DB31	Complex - Medium	Early - Institutional	2	4	1.5208
3DB11	Complex - Medium	Late - Community	0	2	0.7446
3DB21	Complex - Medium	Late - Community	1	2	0.8046
3DB31	Complex - Medium	Late - Community	2	2	0.9341
4DB11	Complex - Medium	Late - Institutional	0	3	1.1930
4DB21	Complex - Medium	Late - Institutional	1	3	1.2530
4DB31	Complex - Medium	Late - Institutional	2	3	1.3825
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	4	1.2257
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	5	1.2857
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	5	1.4152
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	4	1.4023
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	5	1.4623
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	5	1.5918
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	2	0.8156
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	2	0.8756
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	2	1.0051
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	4	1.2641
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	4	1.3241
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	4	1.4536
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	3	0.9036
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	4	0.9636
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	4	1.0931
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	3	1.0802
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	4	1.1402
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	4	1.2697
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	2	0.4935
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	2	0.5535
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	2	0.6830
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	3	0.9420
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	3	1.0020
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	4	1.1315
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	4	1.0669
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	4	1.1270
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	5	1.2564
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	4	1.2435

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)	CY 2020 Weights
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	5	1.3036
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	5	1.4331
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	2	0.6569
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	2	0.7169
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	2	0.8464
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	3	1.1053
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	4	1.1653
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	4	1.2948
1HC11	MMTA - Cardiac - High	Early - Community	0	5	1.2458
1HC21	MMTA - Cardiac - High	Early - Community	1	5	1.3058
1HC31	MMTA - Cardiac - High	Early - Community	2	5	1.4353
2HC11	MMTA - Cardiac - High	Early - Institutional	0	4	1.4224
2HC21	MMTA - Cardiac - High	Early - Institutional	1	4	1.4824
2HC31	MMTA - Cardiac - High	Early - Institutional	2	5	1.6119
3HC11	MMTA - Cardiac - High	Late - Community	0	2	0.8357
3HC21	MMTA - Cardiac - High	Late - Community	1	2	0.8957
3HC31	MMTA - Cardiac - High	Late - Community	2	3	1.0252
4HC11	MMTA - Cardiac - High	Late - Institutional	0	4	1.2841
4HC21	MMTA - Cardiac - High	Late - Institutional	1	4	1.3442
4HC31	MMTA - Cardiac - High	Late - Institutional	2	4	1.4737
1HA11	MMTA - Cardiac - Low	Early - Community	0	4	0.9886
1HA21	MMTA - Cardiac - Low	Early - Community	1	4	1.0487
1HA31	MMTA - Cardiac - Low	Early - Community	2	4	1.1782
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	4	1.1652
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	4	1.2253
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	4	1.3548
3HA11	MMTA - Cardiac - Low	Late - Community	0	2	0.5786
3HA21	MMTA - Cardiac - Low	Late - Community	1	2	0.6386
3HA31	MMTA - Cardiac - Low	Late - Community	2	3	0.7681
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	3	1.0270
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	3	1.0870
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	3	1.2165
1HB11	MMTA - Cardiac - Medium	Early - Community	0	5	1.1315
1HB21	MMTA - Cardiac - Medium	Early - Community	1	5	1.1915
1HB31	MMTA - Cardiac - Medium	Early - Community	2	5	1.3210
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	4	1.3081
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	5	1.3681
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	5	1.4976
3HB11	MMTA - Cardiac - Medium	Late - Community	0	2	0.7214
3HB21	MMTA - Cardiac - Medium	Late - Community	1	2	0.7814
3HB31	MMTA - Cardiac - Medium	Late - Community	2	3	0.9109
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	3	1.1699
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	3	1.2299
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	4	1.3594
1IC11	MMTA - Endocrine - High	Early - Community	0	5	1.3884
1IC21	MMTA - Endocrine - High	Early - Community	1	5	1.4485
1IC31	MMTA - Endocrine - High	Early - Community	2	5	1.5780
2IC11	MMTA - Endocrine - High	Early - Institutional	0	4	1.5650
2IC21	MMTA - Endocrine - High	Early - Institutional	1	5	1.6251
2IC31	MMTA - Endocrine - High	Early - Institutional	2	4	1.7546
3IC11	MMTA - Endocrine - High	Late - Community	0	3	0.9784
3IC21	MMTA - Endocrine - High	Late - Community	1	3	1.0384
3IC31	MMTA - Endocrine - High	Late - Community	2	3	1.1679
4IC11	MMTA - Endocrine - High	Late - Institutional	0	3	1.4268

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)	CY 2020 Weights
4IC21	MMTA - Endocrine - High	Late - Institutional	1	3	1.4868
4IC31	MMTA - Endocrine - High	Late - Institutional	2	4	1.6163
1IA11	MMTA - Endocrine - Low	Early - Community	0	4	1.1216
1IA21	MMTA - Endocrine - Low	Early - Community	1	4	1.1817
1IA31	MMTA - Endocrine - Low	Early - Community	2	4	1.3111
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	3	1.2982
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	4	1.3583
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	4	1.4878
3IA11	MMTA - Endocrine - Low	Late - Community	0	2	0.7116
3IA21	MMTA - Endocrine - Low	Late - Community	1	2	0.7716
3IA31	MMTA - Endocrine - Low	Late - Community	2	3	0.9011
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	3	1.1600
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	3	1.2200
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	3	1.3495
1IB11	MMTA - Endocrine - Medium	Early - Community	0	5	1.2833
1IB21	MMTA - Endocrine - Medium	Early - Community	1	5	1.3434
1IB31	MMTA - Endocrine - Medium	Early - Community	2	4	1.4729
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	4	1.4599
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	4	1.5200
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	5	1.6495
3IB11	MMTA - Endocrine - Medium	Late - Community	0	3	0.8733
3IB21	MMTA - Endocrine - Medium	Late - Community	1	3	0.9333
3IB31	MMTA - Endocrine - Medium	Late - Community	2	3	1.0628
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	3	1.3217
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	3	1.3817
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	4	1.5112
1JC11	MMTA - GI/GU - High	Early - Community	0	4	1.1957
1JC21	MMTA - GI/GU - High	Early - Community	1	3	1.2557
1JC31	MMTA - GI/GU - High	Early - Community	2	3	1.3852
2JC11	MMTA - GI/GU - High	Early - Institutional	0	4	1.3723
2JC21	MMTA - GI/GU - High	Early - Institutional	1	4	1.4323
2JC31	MMTA - GI/GU - High	Early - Institutional	2	4	1.5618
3JC11	MMTA - GI/GU - High	Late - Community	0	2	0.7856
3JC21	MMTA - GI/GU - High	Late - Community	1	2	0.8456
3JC31	MMTA - GI/GU - High	Late - Community	2	2	0.9751
4JC11	MMTA - GI/GU - High	Late - Institutional	0	3	1.2341
4JC21	MMTA - GI/GU - High	Late - Institutional	1	3	1.2941
4JC31	MMTA - GI/GU - High	Late - Institutional	2	4	1.4236
1JA11	MMTA - GI/GU - Low	Early - Community	0	3	0.9567
1JA21	MMTA - GI/GU - Low	Early - Community	1	3	1.0167
1JA31	MMTA - GI/GU - Low	Early - Community	2	3	1.1462
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	3	1.1333
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	4	1.1933
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	4	1.3228
3JA11	MMTA - GI/GU - Low	Late - Community	0	2	0.5466
3JA21	MMTA - GI/GU - Low	Late - Community	1	2	0.6066
3JA31	MMTA - GI/GU - Low	Late - Community	2	2	0.7361
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	3	0.9951
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	3	1.0551
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	3	1.1846
1JB11	MMTA - GI/GU - Medium	Early - Community	0	4	1.1091
1JB21	MMTA - GI/GU - Medium	Early - Community	1	4	1.1691
1JB31	MMTA - GI/GU - Medium	Early - Community	2	4	1.2986
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	4	1.2857

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	4	1.3457
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	4	1.4752
3JB11	MMTA - GI/GU - Medium	Late - Community	0	2	0.6990
3JB21	MMTA - GI/GU - Medium	Late - Community	1	2	0.7590
3JB31	MMTA - GI/GU - Medium	Late - Community	2	2	0.8885
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	3	1.1475
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	3	1.2075
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	4	1.3370
1KC11	MMTA - Infectious - High	Early - Community	0	3	1.2278
1KC21	MMTA - Infectious - High	Early - Community	1	3	1.2878
1KC31	MMTA - Infectious - High	Early - Community	2	3	1.4173
2KC11	MMTA - Infectious - High	Early - Institutional	0	3	1.4044
2KC21	MMTA - Infectious - High	Early - Institutional	1	4	1.4644
2KC31	MMTA - Infectious - High	Early - Institutional	2	4	1.5939
3KC11	MMTA - Infectious - High	Late - Community	0	2	0.8177
3KC21	MMTA - Infectious - High	Late - Community	1	2	0.8777
3KC31	MMTA - Infectious - High	Late - Community	2	2	1.0072
4KC11	MMTA - Infectious - High	Late - Institutional	0	3	1.2661
4KC21	MMTA - Infectious - High	Late - Institutional	1	3	1.3261
4KC31	MMTA - Infectious - High	Late - Institutional	2	3	1.4556
1KA11	MMTA - Infectious - Low	Early - Community	0	3	0.9853
1KA21	MMTA - Infectious - Low	Early - Community	1	3	1.0453
1KA31	MMTA - Infectious - Low	Early - Community	2	4	1.1748
2KA11	MMTA - Infectious - Low	Early - Institutional	0	3	1.1619
2KA21	MMTA - Infectious - Low	Early - Institutional	1	3	1.2219
2KA31	MMTA - Infectious - Low	Early - Institutional	2	4	1.3514
3KA11	MMTA - Infectious - Low	Late - Community	0	2	0.5752
3KA21	MMTA - Infectious - Low	Late - Community	1	2	0.6352
3KA31	MMTA - Infectious - Low	Late - Community	2	2	0.7647
4KA11	MMTA - Infectious - Low	Late - Institutional	0	2	1.0236
4KA21	MMTA - Infectious - Low	Late - Institutional	1	3	1.0836
4KA31	MMTA - Infectious - Low	Late - Institutional	2	3	1.2131
1KB11	MMTA - Infectious - Medium	Early - Community	0	3	1.1174
1KB21	MMTA - Infectious - Medium	Early - Community	1	4	1.1774
1KB31	MMTA - Infectious - Medium	Early - Community	2	4	1.3069
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	4	1.2940
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	4	1.3540
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	5	1.4835
3KB11	MMTA - Infectious - Medium	Late - Community	0	2	0.7073
3KB21	MMTA - Infectious - Medium	Late - Community	1	2	0.7674
3KB31	MMTA - Infectious - Medium	Late - Community	2	2	0.8968
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	3	1.1558
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	3	1.2158
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	4	1.3453
1AC11	MMTA - Other - High	Early - Community	0	5	1.2701
1AC21	MMTA - Other - High	Early - Community	1	5	1.3302
1AC31	MMTA - Other - High	Early - Community	2	5	1.4597
2AC11	MMTA - Other - High	Early - Institutional	0	5	1.4468
2AC21	MMTA - Other - High	Early - Institutional	1	5	1.5068
2AC31	MMTA - Other - High	Early - Institutional	2	5	1.6363
3AC11	MMTA - Other - High	Late - Community	0	2	0.8601
3AC21	MMTA - Other - High	Late - Community	1	3	0.9201
3AC31	MMTA - Other - High	Late - Community	2	3	1.0496
4AC11	MMTA - Other - High	Late - Institutional	0	4	1.3085

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)	CY 2020 Weights
4AC21	MMTA - Other - High	Late - Institutional	1	4	1.3685
4AC31	MMTA - Other - High	Late - Institutional	2	3	1.4980
1AA11	MMTA - Other - Low	Early - Community	0	4	1.0062
1AA21	MMTA - Other - Low	Early - Community	1	4	1.0662
1AA31	MMTA - Other - Low	Early - Community	2	4	1.1957
2AA11	MMTA - Other - Low	Early - Institutional	0	3	1.1828
2AA21	MMTA - Other - Low	Early - Institutional	1	4	1.2428
2AA31	MMTA - Other - Low	Early - Institutional	2	4	1.3723
3AA11	MMTA - Other - Low	Late - Community	0	2	0.5961
3AA21	MMTA - Other - Low	Late - Community	1	2	0.6562
3AA31	MMTA - Other - Low	Late - Community	2	3	0.7856
4AA11	MMTA - Other - Low	Late - Institutional	0	3	1.0446
4AA21	MMTA - Other - Low	Late - Institutional	1	3	1.1046
4AA31	MMTA - Other - Low	Late - Institutional	2	3	1.2341
1AB11	MMTA - Other - Medium	Early - Community	0	5	1.1456
1AB21	MMTA - Other - Medium	Early - Community	1	5	1.2056
1AB31	MMTA - Other - Medium	Early - Community	2	5	1.3351
2AB11	MMTA - Other - Medium	Early - Institutional	0	5	1.3222
2AB21	MMTA - Other - Medium	Early - Institutional	1	5	1.3822
2AB31	MMTA - Other - Medium	Early - Institutional	2	5	1.5117
3AB11	MMTA - Other - Medium	Late - Community	0	2	0.7355
3AB21	MMTA - Other - Medium	Late - Community	1	2	0.7955
3AB31	MMTA - Other - Medium	Late - Community	2	3	0.9250
4AB11	MMTA - Other - Medium	Late - Institutional	0	3	1.1839
4AB21	MMTA - Other - Medium	Late - Institutional	1	3	1.2440
4AB31	MMTA - Other - Medium	Late - Institutional	2	4	1.3735
1LC11	MMTA - Respiratory - High	Early - Community	0	4	1.2081
1LC21	MMTA - Respiratory - High	Early - Community	1	4	1.2681
1LC31	MMTA - Respiratory - High	Early - Community	2	4	1.3976
2LC11	MMTA - Respiratory - High	Early - Institutional	0	4	1.3847
2LC21	MMTA - Respiratory - High	Early - Institutional	1	4	1.4447
2LC31	MMTA - Respiratory - High	Early - Institutional	2	4	1.5742
3LC11	MMTA - Respiratory - High	Late - Community	0	2	0.7980
3LC21	MMTA - Respiratory - High	Late - Community	1	2	0.8581
3LC31	MMTA - Respiratory - High	Late - Community	2	3	0.9876
4LC11	MMTA - Respiratory - High	Late - Institutional	0	3	1.2465
4LC21	MMTA - Respiratory - High	Late - Institutional	1	4	1.3065
4LC31	MMTA - Respiratory - High	Late - Institutional	2	3	1.4360
1LA11	MMTA - Respiratory - Low	Early - Community	0	4	0.9655
1LA21	MMTA - Respiratory - Low	Early - Community	1	4	1.0255
1LA31	MMTA - Respiratory - Low	Early - Community	2	4	1.1550
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	4	1.1421
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	4	1.2021
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	4	1.3316
3LA11	MMTA - Respiratory - Low	Late - Community	0	2	0.5554
3LA21	MMTA - Respiratory - Low	Late - Community	1	2	0.6155
3LA31	MMTA - Respiratory - Low	Late - Community	2	2	0.7450
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	3	1.0039
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	3	1.0639
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	3	1.1934
1LB11	MMTA - Respiratory - Medium	Early - Community	0	4	1.1041
1LB21	MMTA - Respiratory - Medium	Early - Community	1	5	1.1641
1LB31	MMTA - Respiratory - Medium	Early - Community	2	5	1.2936
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	4	1.2807

HIPPS	Clinical Group and Functional Level	Timing and Admission Source	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Visit Threshold (10^{th} percentile or 2 - whichever is higher)	CY 2020 Weights
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	5	1.3407
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	5	1.4702
3LB11	MMTA - Respiratory - Medium	Late - Community	0	2	0.6940
3LB21	MMTA - Respiratory - Medium	Late - Community	1	2	0.7541
3LB31	MMTA - Respiratory - Medium	Late - Community	2	2	0.8835
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	3	1.1425
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	3	1.2025
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	4	1.3320
1EC11	MS Rehab - High	Early - Community	0	5	1.3424
1EC21	MS Rehab - High	Early - Community	1	5	1.4024
1EC31	MS Rehab - High	Early - Community	2	5	1.5319
2EC11	MS Rehab - High	Early - Institutional	0	6	1.5190
2EC21	MS Rehab - High	Early - Institutional	1	6	1.5790
2EC31	MS Rehab - High	Early - Institutional	2	6	1.7085
3EC11	MS Rehab - High	Late - Community	0	2	0.9323
3EC21	MS Rehab - High	Late - Community	1	2	0.9923
3EC31	MS Rehab - High	Late - Community	2	3	1.1218
4EC11	MS Rehab - High	Late - Institutional	0	4	1.3807
4EC21	MS Rehab - High	Late - Institutional	1	4	1.4407
4EC31	MS Rehab - High	Late - Institutional	2	5	1.5702
1EA11	MS Rehab - Low	Early - Community	0	5	1.0847
1EA21	MS Rehab - Low	Early - Community	1	5	1.1447
1EA31	MS Rehab - Low	Early - Community	2	5	1.2742
2EA11	MS Rehab - Low	Early - Institutional	0	5	1.2613
2EA21	MS Rehab - Low	Early - Institutional	1	5	1.3213
2EA31	MS Rehab - Low	Early - Institutional	2	5	1.4508
3EA11	MS Rehab - Low	Late - Community	0	2	0.6746
3EA21	MS Rehab - Low	Late - Community	1	2	0.7347
3EA31	MS Rehab - Low	Late - Community	2	3	0.8642
4EA11	MS Rehab - Low	Late - Institutional	0	4	1.1231
4EA21	MS Rehab - Low	Late - Institutional	1	4	1.1831
4EA31	MS Rehab - Low	Late - Institutional	2	4	1.3126
1EB11	MS Rehab - Medium	Early - Community	0	5	1.1912
1EB21	MS Rehab - Medium	Early - Community	1	5	1.2512
1EB31	MS Rehab - Medium	Early - Community	2	5	1.3807
2EB11	MS Rehab - Medium	Early - Institutional	0	5	1.3678
2EB21	MS Rehab - Medium	Early - Institutional	1	6	1.4278
2EB31	MS Rehab - Medium	Early - Institutional	2	6	1.5573
3EB11	MS Rehab - Medium	Late - Community	0	2	0.7811
3EB21	MS Rehab - Medium	Late - Community	1	2	0.8411
3EB31	MS Rehab - Medium	Late - Community	2	3	0.9706
4EB11	MS Rehab - Medium	Late - Institutional	0	4	1.2295
4EB21	MS Rehab - Medium	Late - Institutional	1	4	1.2896
4EB31	MS Rehab - Medium	Late - Institutional	2	4	1.4191
1BC11	Neuro - High	Early - Community	0	5	1.4555
1BC21	Neuro - High	Early - Community	1	5	1.5155
1BC31	Neuro - High	Early - Community	2	5	1.6450
2BC11	Neuro - High	Early - Institutional	0	5	1.6321
2BC21	Neuro - High	Early - Institutional	1	6	1.6921
2BC31	Neuro - High	Early - Institutional	2	5	1.8216
3BC11	Neuro - High	Late - Community	0	2	1.0454
3BC21	Neuro - High	Late - Community	1	3	1.1054
3BC31	Neuro - High	Late - Community	2	3	1.2349
4BC11	Neuro - High	Late - Institutional	0	4	1.4938

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)	CY 2020 Weights
4BC21	Neuro - High	Late - Institutional	1	4	1.5539
4BC31	Neuro - High	Late - Institutional	2	4	1.6833
1BA11	Neuro - Low	Early - Community	0	5	1.1925
1BA21	Neuro - Low	Early - Community	1	5	1.2526
1BA31	Neuro - Low	Early - Community	2	5	1.3821
2BA11	Neuro - Low	Early - Institutional	0	5	1.3691
2BA21	Neuro - Low	Early - Institutional	1	5	1.4292
2BA31	Neuro - Low	Early - Institutional	2	5	1.5587
3BA11	Neuro - Low	Late - Community	0	2	0.7825
3BA21	Neuro - Low	Late - Community	1	2	0.8425
3BA31	Neuro - Low	Late - Community	2	2	0.9720
4BA11	Neuro - Low	Late - Institutional	0	3	1.2309
4BA21	Neuro - Low	Late - Institutional	1	4	1.2909
4BA31	Neuro - Low	Late - Institutional	2	4	1.4204
1BB11	Neuro - Medium	Early - Community	0	5	1.3508
1BB21	Neuro - Medium	Early - Community	1	5	1.4109
1BB31	Neuro - Medium	Early - Community	2	5	1.5404
2BB11	Neuro - Medium	Early - Institutional	0	6	1.5275
2BB21	Neuro - Medium	Early - Institutional	1	6	1.5875
2BB31	Neuro - Medium	Early - Institutional	2	6	1.7170
3BB11	Neuro - Medium	Late - Community	0	2	0.9408
3BB21	Neuro - Medium	Late - Community	1	2	1.0008
3BB31	Neuro - Medium	Late - Community	2	3	1.1303
4BB11	Neuro - Medium	Late - Institutional	0	4	1.3892
4BB21	Neuro - Medium	Late - Institutional	1	4	1.4492
4BB31	Neuro - Medium	Late - Institutional	2	5	1.5787
1CC11	Wound - High	Early - Community	0	5	1.4985
1CC21	Wound - High	Early - Community	1	5	1.5585
1CC31	Wound - High	Early - Community	2	5	1.6880
2CC11	Wound - High	Early - Institutional	0	4	1.6751
2CC21	Wound - High	Early - Institutional	1	5	1.7351
2CC31	Wound - High	Early - Institutional	2	5	1.8646
3CC11	Wound - High	Late - Community	0	3	1.0884
3CC21	Wound - High	Late - Community	1	3	1.1484
3CC31	Wound - High	Late - Community	2	3	1.2779
4CC11	Wound - High	Late - Institutional	0	3	1.5368
4CC21	Wound - High	Late - Institutional	1	4	1.5969
4CC31	Wound - High	Late - Institutional	2	4	1.7263
1CA11	Wound - Low	Early - Community	0	5	1.2207
1CA21	Wound - Low	Early - Community	1	5	1.2808
1CA31	Wound - Low	Early - Community	2	4	1.4103
2CA11	Wound - Low	Early - Institutional	0	4	1.3974
2CA21	Wound - Low	Early - Institutional	1	4	1.4574
2CA31	Wound - Low	Early - Institutional	2	4	1.5869
3CA11	Wound - Low	Late - Community	0	2	0.8107
3CA21	Wound - Low	Late - Community	1	3	0.8707
3CA31	Wound - Low	Late - Community	2	3	1.0002
4CA11	Wound - Low	Late - Institutional	0	3	1.2591
4CA21	Wound - Low	Late - Institutional	1	3	1.3191
4CA31	Wound - Low	Late - Institutional	2	3	1.4486
1CB11	Wound - Medium	Early - Community	0	5	1.3743
1CB21	Wound - Medium	Early - Community	1	5	1.4343
1CB31	Wound - Medium	Early - Community	2	5	1.5638
2CB11	Wound - Medium	Early - Institutional	0	5	1.5509

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)	CY 2020 Weights
2CB21	Wound - Medium	Early - Institutional	1	5	1.6109
2CB31	Wound - Medium	Early - Institutional	2	5	1.7404
3CB11	Wound - Medium	Late - Community	0	3	0.9642
3CB21	Wound - Medium	Late - Community	1	3	1.0242
3CB31	Wound - Medium	Late - Community	2	3	1.1537
4CB11	Wound - Medium	Late - Institutional	0	4	1.4126
4CB21	Wound - Medium	Late - Institutional	1	4	1.4727
4CB31	Wound - Medium	Late - Institutional	2	4	1.6022

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018 (as of March 27, 2019) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

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E. Proposed CY 2020 Home Health Payment Rate Updates

1. Proposed CY 2020 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2020 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. In the CY 2019 HH PPS final rule (83 FR 56425), we finalized a rebasing of the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and complete data on the actual structure of HHA costs. As such, based on the rebased 2016-based home health market basket, we finalized that the labor-related share is 76.1 percent and the non-labor-related share is 23.9 percent. A detailed description of how we rebased the HHA market basket is available in the CY 2019 HH PPS final rule (83 FR 56425 through 56436).

Section 1895(b)(3)(B) 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)), and except in CY 2020 (under section 53110 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123, enacted February 9, 2018)), 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.

The proposed home health update percentage for CY 2020 would have been based on the estimated home health market basket update, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.0 percent (based on IHS Global Insight Inc.'s first-quarter 2019 forecast with historical data through fourth-quarter 2018). Due to the requirements specified at section 1895(b)(3)(B)(vi) of the Act prior to the enactment of the BBA of 2018, the estimated CY 2020 home health market basket update of 3.0 percent would have been reduced by a MFP adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148) and currently estimated to be 0.4 percentage point for CY 2020. In effect, the proposed home health payment update percentage for CY 2020 would have been a 2.6 percent increase. However, section 53110 of the BBA of 2018 amended section 1895(b)(3)(B) of the Act, such that for home health payments for CY 2020, the home health payment update is required to be 1.5 percent. The MFP adjustment is not applied to the BBA of 2018 mandated 1.5 percent payment update. 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 2020, the home health payment update would be −0.5 percent (1.5 percent minus 2 percentage points).

2. CY 2020 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 propose to continue this practice for CY 2020, 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 propose to use the FY 2020 pre-floor, pre-reclassified hospital wage index as the CY 2020 wage adjustment to the labor portion of the HH PPS rates. For CY 2020, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2015, and before October 1, 2016 (FY 2016 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 2020 HH PPS wage index, we propose 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 propose 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 propose 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 2020, the urban areas without inpatient hospital wage data are Hinesville, GA (CBSA 25980) and Carson City, NV (CBSA 16180). The CY 2020 wage index value for Hinesville, GA is 0.8237 and the wage index value for Carson City, NV is 1.0518.

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan 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. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2020 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8252. Bulletin No. 17–01 is available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*[13]

The most recent OMB Bulletin (No. 18–04) was published on September 14, 2018 and is available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*[14]

The revisions contained in OMB Bulletin No. 18–04 have no impact on the geographic area delineations that are used to wage adjust HH PPS payments.

The CY 2020 wage index is available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.* We were recently made aware of a minor calculation error in the file used to compute the home health wage index values. We are also posting the corrected wage index values in the same file, on the same website and we will correct this error when computing the home health wage index values and payment rates for the final rule.

3. Comment Solicitation

Historically, we have calculated the home health wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the home health wage index values and their impact on payments. We are soliciting comments on concerns stakeholders may have regarding the wage index used to adjust home health payments and suggestions for possible updates and improvements to the geographic adjustment of home health payments.

4. CY 2020 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 was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule (83 FR 56406) and as described in section III.B of this proposed rule, the unit of home health payment will change from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020. However, the standardized 60-day payment rate will apply to case-mix adjusted episodes (that is, not LUPAs) beginning on or before December 31, 2019 and ending on or before February 28, 2020. As such, the latest date such a 60-day crossover episode could end on is February 28, 2020. Those 60-day episodes that begin on or before December 31, 2019, but are LUPA episodes, will be paid the national, per-visit payment rates as shown in Table 23.

As set forth in § 484.220, we adjust the national, standardized prospective payment rates 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. In the CY 2019 HH PPS final rule (83 FR 56435), we finalized 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. We also finalized a revision to the labor-related share to reflect the 2016-based home health market basket Compensation (Wages and Salaries plus Benefits) cost weight. We finalized that for CY 2019 and subsequent years, the labor-related share would be 76.1 percent and the non-labor-related share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode (for those episodes that span the implementation date of January 1, 2020) and 30-day period rates for CY 2020:

- Multiply the national, standardized 60-day episode rate or 30-day period 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 or 30-day period rate, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate or 30-day period rate is equal to the rate for the previous calendar year increased by the applicable HH payment update, 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 both the national, standardized 60-day and 30-day case-mix and wage-adjusted payment amounts on a split percentage payment approach for those HHAs eligible for such payments. The split percentage payment approach includes an initial percentage payment and a final

[13] "Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas". OMB BULLETIN NO. 17–01. August 15, 2017. *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

[14] Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas". OMB BULLETIN NO. 18–04. September 14, 2018. *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

percentage payment as set forth in § 484.205(b)(1) and (2). The claim that the HHA submits for the final percentage payment determines the total payment amount for the episode or period and whether we make an applicable adjustment to the 60-day or 30-day case-mix and wage-adjusted payment amount. We refer stakeholders to section III.H. of this proposed rule regarding proposals on changes to the current split percentage policy in CY 2020 and subsequent years. The end date of the 60-day episode or 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day or 30-day case-mix and wage-adjusted 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(d)(1) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

b. CY 2020 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the standard, prospective payment 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 2020 national, standardized 60-day episode payment rate for those 60-day episodes that span the implementation date of the PDGM and the change to a 30-day unit of payment, we apply a wage index budget neutrality factor and the home health payment update percentage discussed in section III.F.1. of this proposed rule. We are not proposing to update the case-mix weights for the 153-group case-mix methodology in CY 2020 as outlined in section III.D. of this proposed rule. Because we would continue to use the CY 2019 case-mix weights, we do not have to apply a case-mix weight budget neutrality factor to the CY 2020 60-day episode payment rate.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2020 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2019 wage index. By dividing the total payments for non-LUPA episodes using the CY 2020 wage index by the total payments for non-LUPA episodes using the CY 2019 wage index, we obtain a wage index budget neutrality factor of 1.0062. We would apply the wage index budget neutrality factor of 1.0062 to the calculation of the CY 2019 national, standardized 60-day episode payment rate.

Next, we would update the 60-day payment rate by the CY 2020 home health payment update percentage of 1.5 percent as required by section 53110 of the BBA of 2018 and as described in section III.E.1. of this proposed rule. The CY 2020 national, standardized 60-day episode payment rate is calculated in Table 15.

TABLE 15: CY 2020 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2019 National, Standardized 60-Day Episode Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update	CY 2020 National, Standardized 60-Day Episode Payment
$3,154.27	X 1.0062	X 1.015	$3,221.43

The CY 2020 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2020 home health payment update of 1.5 percent minus 2 percentage points and is shown in Table 16.

TABLE 16: CY 2020 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2019 National, Standardized 60-Day Episode Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update Minus 2 Percentage Points	CY 2020 National, Standardized 60-Day Episode Payment
$3,154.27	X 1.0062	X 0.995	$3,157.96

c. CY 2020 Non-Routine Medical Supply (NRS) Payment Rates for CY 2020 60-Day Episodes of Care

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, IV 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

2020 NRS conversion factor, we updated the CY 2019 NRS conversion factor ($54.20) by the CY 2020 home health payment update percentage of 1.5 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 proposed NRS conversion factor for CY 2020 is shown in Table 17.

TABLE 17: CY 2020 NRS CONVERSION FACTOR

CY 2019 NRS Conversion Factor	CY 2020 HH Payment Update	CY 2020 NRS Conversion Factor
$54.20	X 1.015	$55.01

Using the CY 2020 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 18.

TABLE 18: CY 2020 NRS PAYMENT AMOUNTS

Severity Level	Points (Scoring)	Relative Weight	CY 2020 NRS Payment Amounts
1	0	0.2698	$14.84
2	1 to 14	0.9742	$53.59
3	15 to 27	2.6712	$146.94
4	28 to 48	3.9686	$218.31
5	49 to 98	6.1198	$336.65
6	99+	10.5254	$579.00

For HHAs that do not submit the required quality data, we updated the CY 2019 NRS conversion factor ($54.20) by the CY 2019 home health payment update percentage of 1.5 percent minus 2 percentage points. To determine the CY 2020 NRS conversion factor for HHAs that do not submit the required quality data we multiplied the CY 2019 NRS conversion factor ($54.20) by the CY 2020 HH Payment Update (0.995) to determine the CY 2020 NRS conversion factor ($53.93). The proposed CY 2020 NRS conversion factor for HHAs that do not submit quality data is shown in Table 19.

TABLE 19: CY 2020 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2019 NRS Conversion Factor	CY 2020 HH Payment Update Percentage Minus 2 Percentage Points	CY 2020 NRS Conversion Factor
$54.20	X 0.995	$53.93

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 20.

TABLE 20: CY 2020 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity Level	Points (Scoring)	Relative Weight	CY 2020 NRS Payment Amounts
1	0	0.2698	$ 14.55
2	1 to 14	0.9742	$ 52.54
3	15 to 27	2.6712	$ 144.06
4	28 to 48	3.9686	$ 214.03
5	49 to 98	6.1198	$ 330.04
6	99+	10.5254	$ 567.63

In CY 2020, the NRS payment amounts apply to only those 60-day episodes that begin on or before December 31, 2019 but span the implementation of the PDGM and the 30-day unit of payment on January 1, 2020 (ending on February 28, 2020). Under the PDGM, NRS payments are included in the 30-day base payment rate.

d. CY 2020 National, Standardized 30-Day Period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment 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 2020 national, standardized 30-day period payment rate, we apply a wage index budget neutrality factor; and the home health payment update percentage discussed in section III.E.1. of this proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2020 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2019 wage index. By dividing the total payments for non-LUPA episodes using the CY 2020 wage index by the total payments for non-LUPA episodes using the CY 2019 wage index, we obtain a wage index budget neutrality factor of 1.0062. We would apply the wage index budget neutrality factor of 1.0062 to the calculation of the CY 2019 national, standardized 30-day period payment rate as described in section III.B. of this proposed rule.

We note that in past years, a case-mix budget neutrality factor was annually applied to the HH PPS base rates to account for the change between the previous year's case-mix weights and the newly recalibrated case-mix weights. Since CY 2020 is the first year of PDGM, there is no way to do a case-mix budget neutrality factor in this manner. However, in future years under the PDGM, we would apply a case-mix budget neutrality factor with the annual payment update in order to account for the change between the previous year's PDGM case-mix weights.

Next, we would update the 30-day payment rate by the CY 2020 home health payment update percentage of 1.5 percent as required by section 53110 of the BBA of 2018 and as described in section III.F.1. of this proposed rule. The CY 2020 national, standardized 30-day period payment rate is calculated in Table 21.

TABLE 21: CY 2020 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2020 30-day Budget Neutral (BN) Standard Amount	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update	CY 2020 National, Standardized 30-Day Period Payment
$1,754.37	X 1.0062	X 1.015	$1,791.73

The CY 2020 national, standardized 30-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2020 home health payment update of 1.5 percent minus 2 percentage points and is shown in Table 22.

TABLE 22: CY 2020 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2019 National, Standardized 30-Day Period Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update Minus 2 Percentage Points	CY 2020 National, Standardized 30-Day Period Payment
$1,754.37	X 1.0062	X 0.995	$1,756.42

e. CY 2020 National Per-Visit Rates for Both 60-Day Episodes of Care and 30-Day Periods of Care

The national per-visit rates are used to pay LUPAs 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 2020 national per-visit rates, we started with the CY 2019 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 2020 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2019 wage index. By dividing the total payments for LUPA episodes using the CY 2020 wage index by the total payments for LUPA episodes using the CY 2019 wage index, we obtained a wage index budget neutrality factor of 1.0066. We apply the wage index budget neutrality factor of 1.0066 in order to calculate the CY 2020 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 2020 home health payment update percentage of 1.5 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 2020 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2020 HH payment update percentage of 1.5 percent and are shown in Table 23.

TABLE 23: CY 2020 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2019 Per-Visit Payment	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update	CY 2020 Per-Visit Payment
Home Health Aide	$66.34	X 1.0065	X 1.015	$ 67.77
Medical Social Services	$234.82	X 1.0065	X 1.015	$239.89
Occupational Therapy	$161.24	X 1.0065	X 1.015	$164.72
Physical Therapy	$160.14	X 1.0065	X 1.015	$163.60
Skilled Nursing	$146.50	X 1.0065	X 1.015	$149.66
Speech-Language Pathology	$174.06	X 1.0065	X 1.015	$177.82

The CY 2020 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2020 HH payment update percentage of 1.5 percent minus 2 percentage points and are shown in Table 24.

TABLE 24: CY 2020 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2019 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2020 HH Payment Update Minus 2 Percentage Points	CY 2020 Per-Visit Rates
Home Health Aide	$66.34	X 1.0065	X 0.995	$66.44
Medical Social Services	$234.82	X 1.0065	X 0.995	$235.16
Occupational Therapy	$161.24	X 1.0065	X 0.995	$161.48
Physical Therapy	$160.14	X 1.0065	X 0.995	$160.38
Skilled Nursing	$146.50	X 1.0065	X 0.995	$146. 71
Speech- Language Pathology	$174.06	X 1.0065	X 0.995	$174.32

f. Rural Add-On Payments for CYs 2020 Through 2022

1. Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) 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 Deficit Reduction Act of 2003 (DRA) (Pub. L. 108–171) 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 BBA 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 2020 Through 2022

Section 50208(a)(1)(D) of the BBA of 2018 added a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes or visits ending during CYs 2019 through 2022. It also mandated implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provided 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).

In the CY 2019 HH PPS final rule (83 FR 56443), CMS finalized policies for the rural add-on payments for CY 2019 through CY 2022, in accordance with section 50208 of the BBA of 2018. The CY 2019 HH PPS proposed rule (83 FR 32373) described the provisions of the rural add-on payments, the methodology for applying the new payments, and outlined how we categorized rural counties (or equivalent areas) based on claims data, the Medicare Beneficiary Summary File and Census data. The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.* In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) state and county codes, and their designation into one of the three rural add-on categories is available for download.

The HH PRICER module, located within CMS' claims processing system, will increase the proposed CY 2020 60-day and 30-day base payment rates described in section III.E. of this proposed rule by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2020 through 2022 rural add-on percentages outlined in law are shown in Table 25.

TABLE 25: HH PPS RURAL ADD-ON PERCENTAGES, CYs 2020-2022

Category	CY 2020	CY 2021	CY 2022
High utilization	0.5%	None	None
Low population density	3.0%	2.0%	1.0%
All other	2.0%	1.0%	None

g. Low-Utilization Payment Adjustment (LUPA) Add-On Factors and Partial Payment Adjustments

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. 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.

In the CY 2019 HH PPS final rule (83 FR 56440), we finalized our policy of continuing 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. For example, using the proposed CY 2020 per-visit payment rates for those HHAs that submit the required quality data, for LUPA periods that occur as the only period or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit will be $276.14 (1.8451 multiplied by $149.66), subject to area wage adjustment.

Also in the CY 2019 HH PPS final rule (83 FR 56516), we finalized our policy that the process for partial payment adjustments for 30-day periods of care will remain the same as the process for 60-day episodes. The partial episode payment (PEP) adjustment is a proportion of the period payment and is based on the span of days including the start-of-care date (for example, the date of the first billable service) through and including the last billable service date under the original plan of care before the intervening event in a home health beneficiary's care defined as a—

- Beneficiary elected transfer, or
- 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.

When a new 30-day period begins due to an intervening event, the original 30-day period will 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 will 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 the 30-day period. The proportion will then be multiplied by the original case-mix and wage index to produce the 30-day payment.

F. Proposed Payments for High-Cost Outliers Under the H 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 that surpasses 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 to require that the Secretary 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 re-designating 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 for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted 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 targeted 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 2020 in the rate update change request, which is issued after the publication of the CY 2020 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.

In the CY 2019 HH PPS final rule (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of the PDGM beginning in CY 2020 and that we will calculate payment for high-cost outliers based upon 30-day periods of care. The calculation of the proposed fixed-dollar loss ratio for CY 2020 for both the 60-day episodes that span the implementation date, and for 30-day periods of care beginning on and after January 1, 2020 is detailed in this section.

2. Proposed Fixed Dollar Loss (FDL) Ratio for CY 2020

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 or periods 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 or periods. Alternatively, a lower FDL ratio means that more episodes or periods can qualify for outlier payments, but outlier payments per episode or per period 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 that exceed the outlier threshold amount.

In the CY 2019 HH PPS final rule (83 FR 56439), we finalized a FDL ratio of 0.51 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. For CY 2020, we are not proposing to update the FDL ratio for those 60-day episodes that span the implementation date of the PDGM; we would keep the FDL ratio for 60-day episodes in CY 2020 at 0.51. For this CY 2020 proposed rule, simulating payments using preliminary CY 2018 claims data (as of January 2019) and the CY 2019 HH PPS payment rates, we estimate that outlier payments in CY 2019 would comprise 2.42 percent of total payments for those 60-day episodes that span into 2020 and are paid under the national, standardized 60-day payment rate (with an FDL of 0.51) and 2.5 percent of total payments for PDGM 30-day periods using the 30-day budget-neutral payment amount as detailed in section III.B. of this proposed rule (with an FDL of 0.63). Given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are proposing that the FDL ratio for 30-day periods of care in CY 2020 would need to be set at 0.63 for 30-day periods of care based on our simulations looking at both 60-day episodes that would span into CY 2020 and 30-day periods. We note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2018 claims data as of June 30, 2019 or later) and therefore, we may adjust the final FDL ratio accordingly. We invite public comments on the proposed change to the FDL ratio for CY 2020.

G. Proposed Changes to the Split-Percentage Payment Approach for HHAs in CY 2020 and Subsequent Years

1. Background

In the current HH PPS, there is a split-percentage payment approach to the 60-day episode of care. 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. RAP submissions are operationally significant, as the RAP establishes the beneficiary's primary HHA by alerting the claims processing system consolidating billing edits.

In the CY 2018 HH PPS proposed rule (82 FR 35270), we solicited comments as to whether the split-percentage payment approach would still be needed for HHAs to maintain adequate cash flow if the unit of payment changes from a 60-day episode to a 30-day period; ways to phase-out the split-percentage payment approach, including reducing the percentage of

upfront payment incrementally over a period of time; and if the split-percentage payment approach was ultimately eliminated, whether submission of a Notice of Admission (NOA) within 5 days of the start of care would be needed to establish the primary HHA so the claims processing system would be alerted to a home health period of care. Commenters generally expressed support for continuing the split-percentage payment approach in the future under the proposed alternative case-mix model. While we solicited comments on the possibility of phasing-out the split-percentage payment approach in the future and the need for a NOA, commenters did not provide suggestions for a phase-out approach, but stated that they did not agree with requiring a NOA, given their experience with a similar process under the Medicare hospice benefit. We did not finalize the change to a 30-day unit of payment in the CY 2018 HH PPS final rule to allow CMS more time to examine the effects of such change to a 30-day unit of payment and to an alternate case-mix methodology.

Section 1895(b)(2)(B) of the Act, as added by section 51001(a) of the BBA of 2018, requires that CMS move to a 30-day payment period from a 60-day payment period, effective January 1, 2020. As such, in the CY 2019 HH PPS proposed rule (83 FR 32391), we proposed a change to the split-percentage payment approach where newly-enrolled HHAs, meaning HHAs that were certified for participation in Medicare on or after January 1, 2019, would not receive split-percentage payments beginning in CY 2020. We also 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. Additionally, we proposed that existing HHAs, that is, HHAs certified for participation in Medicare effective prior to January 1, 2019, would continue to receive split-percentage payments upon implementation of the PDGM and the 30-day unit of payment in CY 2020. For split-percentage payments to be made, we proposed that 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, we proposed that 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.

Many commenters supported all or parts of the split-percentage payment proposals. Some commenters stated that elimination of the split-percentage payments would align better with a 30-day payment and would simplify home health claims submissions. Other commenters generally expressed support for continuing the split-percentage payment approach under the PDGM and disagreed with any future phase-out because of a potential impact on cash flow. Others supported eventual elimination of split-percentage payments but wanted ample time to adapt to the PDGM and suggested a multi-year phase-out approach. Some commenters supported elimination of split-percentage payments for late periods of care but suggested that the split-percentage payments should continue for early periods to ensure an upfront payment for newly admitted home health patients. Ultimately, we finalized all of the split-percentage payments proposals in the CY 2019 HH PPS final rule (83 FR 56463), discussed previously.

2. CY 2019 HH PPS Final Rule Title Error Correction

In the CY 2019 HH PPS final rule with comment (83 FR 56628), we finalized that newly-enrolled HHAs, that is HHAs certified for participation in Medicare effective on or after January 1, 2019, will not receive split-percentage payments beginning in CY 2020. HHAs that are certified for participation in Medicare effective on or after January 1, 2019, will still be required to submit a ''no pay'' Request for Anticipated Payment (RAP) at the beginning of a period 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 with effective dates prior to January 1, 2019, would continue to receive split-percentage payments upon implementation of the PDGM and the change to a 30-day unit of payment in CY 2020. We finalized the corresponding regulations text changes at § 484.205(g)(2), which sets forth the policy for split-percentage payments for periods of care on or after January 1, 2020.

However, after the final rule was published, we note that there was an error in titling when the CY 2019 HH PPS final rule went to the **Federal Register**. Specifically, paragraph (g)(2)(ii) is incorrectly titled ''Split percentage payments on or after January 1, 2019''. The title of this paragraph implies that split percentage payments are made to newly-enrolled HHAs on or after January 1, 2019, which is contradictory to the finalized policy on split percentage-payments for newly enrolled HHAs beginning in CY 2020. As such, we are proposing to make a correction to the regulations text at § 484.205(g)(2)(iii) to accurately reflect the finalized policy that newly-enrolled HHAs will not receive split-percentage payments beginning in CY 2020. The regulation at § 484.205(g)(2)(iii), as it relates to split percentage payments for newly-enrolled HHAs under the HH PPS beginning in CY 2020, is separate from the placement of new HHAs into a provisional period of enhanced oversight under the authority of section 6401(a)(3) of the Affordable Care Act, which amended section 1866(j)(3) of the Act. The provisional period of enhanced oversight became effective in February 2019. More information regarding the provisional period of enhanced oversight can be found at the following link: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19005.pdf*

3. CY 2020 and Subsequent Years

CMS continues to believe that, as a result of a reduced timeframe for the unit of payment from a 60-day episode of care to a 30-day period of care, a split-percentage payment approach may not be needed for HHAs to maintain an adequate cash flow. We also believe that a one-time submission of a NOA followed by home health claims submission on a 30-day basis may streamline claims processing for HHAs. Additionally, our analysis has shown that approximately 5 percent of RAPs are not submitted until the end of a 60-day episode of care, 10 percent of RAPs are not submitted until 36 days after the start of the 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 of care (82 FR 35307). We believe that these data are inconsistent with the stated justification for RAPs maintaining adequate cash flow, especially given the change from a 60- to 30-day unit of payment, and increases complexity for HHAs in their claim submission processing. With the change to monthly billing in CY 2020, HHAs should have the ability to maintain an ongoing cash flow, which we believe mitigates concerns for the continued need of a split-percentage payment.

We did not finalize any changes to RAP payments for existing HHAs in the CY 2019 HH PPS final rule (83 FR 56462), we stated that we would monitor RAP submissions, service

utilization, payment and quality trends which may change as a result of implementing the PDGM and a 30-day unit of payment. We also stated if changes in practice and/or coding patterns or RAPs submissions arise, we may propose additional changes in policy.

We have observed that RAP payments pose a significant program integrity risk to the Medicare program, as the current RAP structure pays HHAs 50 to 60 percent of the total episode payment upfront. Currently, RAP payments are automatically recouped against other payments if the claim for a given episode does not follow the RAP submission in the later of: (1) 120 days from the start of the episode; or (2) 60 days from the payment date of the RAP. As stated in the CY 2019 HH PPS proposed rule (83 FR 32391), some fraud schemes have involved HHAs collecting RAP payments, never submitting final claims, and ceasing business before CMS is aware of the need to take action.

Under a typical RAP fraud scenario, a large amount of RAPs are submitted in a short period of time, which could potentially result in payments of millions of dollars within days of the submissions. The 60-day or 120-day time period before a RAP cancellation is triggered in the Fiscal Intermediary Standard System (FISS) is long enough to allow a provider to continue to submit RAPs before we can identify that the final claims are not being submitted and services are not being rendered, and yet is too short for us to perform the necessary investigative steps, such as medical reviews, site verifications, and beneficiary interviews, to determine if fraudulent actions have been conducted. The current payment regulations also allow discharges and readmissions during a home health payment episode, which means that some HHAs can submit multiple RAPs for the same provider/patient combination during the same episode of care.

This type of fraud scheme has been most prevalent among existing providers. As a variation on this scheme, individuals with the intent of perpetuating this fraud enter the Medicare program by acquiring existing HHAs, allowing them to circumvent Medicare's screening and enrollment process. For example, during the screening process, we deny enrollment if owners listed on the enrollment form have certain criminal backgrounds. However, some providers who acquire HHAs fail to disclose ownership changes and as a result, the newly purchased HHA is not subject to the normal enrollment screening process leaving us blind to potentially problematic criminal histories. There are cases where we would have denied enrollment based on a new owner's prior criminal background, but we approve the enrollment of the purchasing entity due to the intentional omission of the new owner and his criminal history. More specifically, individuals intent on perpetrating the HH RAP fraud have taken advantage of the acquisition of existing agencies through Changes of Ownership (CHOWs) and Changes of Information, failing to disclose ownership changes for those HH entities to CMS. A CHOW results in the transfer of a previous owner's Medicare Identification Number and provider agreement (including the previous owner's outstanding Medicare debts) to a new owner and must be reported within 30 days. A Change of Information must be submitted for various types of changes of information on an enrollment. For instance, a change in ownership other than a CHOW—such as the sale of stock from one of several 5 percent or more owners, who is no longer an owner, to a new individual who has become a 5 percent or more owner—also must be reported within 30 days of the change (see § 424.516(e)). Based on our investigations, individuals perpetrating the RAP fraud fail to disclose ownership or informational changes, which results in the changes not being reflected in the Provider Enrollment, Chain, and Ownership System (PECOS), the online Medicare provider and suppler enrollment system that allows registered users to securely and electronically submit and manage Medicare enrollment information. The lack of information concerning changes in ownership contributes to the perpetuation of HH RAP fraud.

CMS has monitored numerous schemes like this where an existing HHA undergoes an unreported ownership change and CMS identifies a massive spike in RAP submissions with no final claims ever being submitted. These types of RAP fraud cases are difficult to investigate because the actual owners perpetrating the fraud are often not the owners identified in PECOS due to a failure to disclose ownership changes. This complicates investigations and results in the need for additional resources to perform extensive manual research of Secretary of States' (SOS) and licensing agencies' websites. In several cases, the individuals perpetrating the fraud have been found to be located outside the country.

The following are examples of HHAs that were identified for billing large amounts of RAPs after a CHOW, or the acquisition of an existing agency, from 2014 to the present.

- Example 1: One prior investigation illustrates an individual intent on perpetrating the HH RAP fraud who took advantage of the acquisition of an existing agency. The investigation was initiated based on a lead generated by the Fraud Prevention System (FPS). Per PECOS, the provider had an effective date that was followed by a CHOW. The investigation was aided by a whistleblower coming forward who stated that the new owners of the agency completed the transaction with the intent to submit large quantities of fraudulent claims with the expressed purpose of receiving inappropriate payment from Medicare. Notwithstanding the quick actions taken to prevent further inappropriate payments, the fraud scheme resulted in improper payments of RAPs and final claims in the amount of $1.3 million.
- Example 2: One investigation, CY 2019 HH PPS proposed rule (83 FR 32391), involved a HHA located in Michigan that submitted home health claims for beneficiaries located in California and Florida. Further analysis found that after a CHOW the HHA submitted RAPs with no final claims. CMS discovered that the address of record for the HHA was vacant for an extended period of time. In addition, we determined that although the HHA had continued billing and receiving payments for RAP claims, it had not submitted a final claim in 10 months. Ultimately, the HHA submitted a total of $50,234,430 in RAP claims and received $37,204,558 in RAP payments.
- Example 3: A HHA submitted a significant spike in the number of RAPs following an ownership change. The investigation identified that in the period following the CHOW there were RAP payments totaling $12 million and thousands of RAPs that were submitted for which apparently no services were rendered.
- Example 4: An Illinois HHA was identified through analysis of CHOW information. Three months after, the HHA had a CHOW, the provider submitted a spike in RAP suppressions. All payments to the provider were suspended. Notwithstanding, the provider was paid $3.6 million in RAPs.

We have attempted to address these types of vulnerabilities through extensive monitoring and investigations. However, there continues to be cases of individual HHAs causing large RAP fraud losses.

In the CY 2019 HH PPS final rule (83 FR 56462), we stated our 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 in order to address unusual billing patterns and potential fraud related to RAP payments to existing providers. In light of the issues outlined in this section, we have determined that the program integrity concerns based upon the current RAP structure are significant enough to revisit the continued need for RAP payments for existing HHAs and propose a phase-out approach to RAP payments.

Therefore, we are proposing a reduction of the split-percentage payment in CY 2020 for existing HHAs and elimination of split-percentage payments for all providers in CY 2021, along with corresponding regulations text changes at § 484.205. Specifically, we are proposing, for existing HHAs (that is, HHAs certified for participation in Medicare with effective dates prior to January 1, 2019): (1) To reduce the split-percentage payment from the current 60/50 percent (dependent on whether the RAP is for a new or subsequent period of care) to 20 percent in CY 2020 for all 30-day HH periods of care (both initial and subsequent periods of care); and (2) full elimination of the split-percentage payments for all providers in CY 2021. We believe that the proposed phase-out approach of split-percentage payments with a reduction to a 20 percent split-percentage payment in CY 2020 allows HHAs time to adjust to a no-RAP environment and provides sufficient time for software and business process changes for a CY 2021 implementation. The current split-percentage payments are 60/40 (for initial episodes of care) and 50/50 (for subsequent episodes of care); therefore, we believe that the reduction in the split-percentage payment must be sufficient enough in order to mitigate the perpetuation of fraud schemes. As such, we believe a reduction to the split percentage payment to 20 percent would achieve this purpose. However, the 20 percent split percentage payment would still provide some upfront payment as HHAs transition from receiving split-percentage payments to receiving full payments on a 30-day basis.

Additionally, we are proposing that newly enrolled HHAs, that is, HHAs enrolled in Medicare on or after January 1, 2019 (and would not receive split-percentage payments beginning in CY 2020), would continue to submit ''no-pay'' RAPs at the beginning of every 30-day period in CY 2020. Beginning in CY 2021, we are proposing that all HHAs would receive the full 30-day period of care payment once the final claim is submitted to CMS.

Beginning in CY 2021, we are also proposing that all HHAs submit a one-time submission of a NOA within 5 calendar days of the start of care to establish that the beneficiary is under a Medicare home health period of care. The NOA would be used to trigger HH consolidated billing edits, required by law under section 1842(b)(6)(F) of the Act, and would allow for other providers and the CMS claims processing systems to know that the beneficiary is in a HH period of care. We are proposing that the NOA be submitted only at the beginning of the first 30-day period of care (that is, the NOA would not have to be submitted for each subsequent 30-day period of care) to establish that the beneficiary is under a home health period of care. However, if there is any beneficiary discharge from home health services and subsequent readmission, a new NOA would need to be submitted within 5 calendar days of an initial 30-day period of care.

When we solicited comments in the CY 2019 HH PPS proposed rule (83 FR 32390) on requiring HHAs to submit a NOA within 5 days of the start of care if the split-percentage payment approach was eliminated, commenters stated that they did not agree with requiring a NOA given the experience with a similar Notice of Election (NOE) process under the Medicare hospice benefit where there were submission issues causing untimely filed NOEs. However, implementation of the Electronic Data Interchange (EDI) submission of hospice Notices of Election (NOE) in January 2018 has alleviated the issues related to the submission of the hospice NOE by increasing efficiency and information exchange coordination. As such, we are proposing that the home health NOA process would be through an EDI submission, similar to that used for submission of the hospice NOE. An EDI submission occurs when NOEs or NOAs are submitted through an electronic data interchange for the purpose of minimizing data entry errors. Because there is already a Medicare claims processing notification of a benefit admission process in place, we believe that this should make the home health NOA process more consistent and timely for HHAs.

Furthermore, because of the reduced timeframe for the unit of payment from a 60-day episode of care to a 30-day period of care and the proposed elimination of RAPs, NOAs would be needed for home health period of care identification (83 FR 32390). Without such notification triggering the home health consolidated billing edits establishing the home health period of care in the common working file (CWF), there could be an increase in claims denials. Subsequently, this potentially could result in an increase in appeals and an increase in situations where other providers, including other HHAs, would not have easily accessible information on whether a patient was already being treated by another HHA. In the CY 2019 HH PPS final rule, while some commenters expressed their concern about potential submission issues and claims delays which could result from the potential use of a NOA, one national association was in support of such proposal. The association strongly recommended CMS require HHAs to submit a NOA within 5 calendar days from the start of care to ensure that the proper agency is established as the primary HHA for the beneficiary and so that the claims processing system is alerted that a beneficiary is under an HHA period of care to enforce the consolidated billing edits required by law.

We are proposing that failure to submit a timely NOA would result in a reduction to the 30-day Medicare payment amount, from the start of care date to the NOA filing date, as is done similarly in hospice. As hospice is paid a bundled per diem payment amount for each day a beneficiary is under a hospice election, Medicare will not cover and pay for the days of hospice care from the hospice admission date to the date the NOE is submitted to the Medicare contractor. Therefore, we are proposing that the penalty for not submitting a timely home health NOA would result in Medicare not paying for those days of home health services from the start of care date to the NOA filing date.

Since payment under home health is a bundled payment, which includes a national, standardized 30-day period payment rate adjusted for case-mix and geographic wage differences, we are proposing that the payment reduction would be applied to the case-mix and wage-adjusted 30-day period payment amount, including NRS. As such, we are proposing that the penalty for not submitting a timely NOA would be a 1/30 reduction off of the full 30-day period payment amount for each day until the date the NOA is submitted (that is, from the start of care date through the day before the NOA is submitted, as the day of submission would be a covered day). The reduction (R) to the full 30-day period payment amount would be calculated as follows:

- The number of days (d) from the start of care until the NOA is submitted divided by 30 days;
- The fraction from step 1 is multiplied by the case-mix and wage adjusted 30-day period payment amount (P).

The formula for the reduction would be $R = (d/30) \times P$.

There would be no NOA penalty if the NOA is submitted timely (that is, within the first 5 calendar days starting with the start of care date). Likewise, we propose that for periods of care in which an HHA fails to submit a timely NOA, no LUPA payments would be made for days that fall within the period of care prior to the submission of the NOA. We are proposing that these days would be a provider liability, the payment reduction could not exceed the total payment of the claim, and that the provider may not bill the beneficiary for these days. Once the NOA is received, all claims for both initial and subsequent episodes of care would compare the receipt date of the NOA to the HH period of care start date to determine whether a late NOA reduction applies.

However, we are also proposing that if an exceptional circumstance is experienced by the HHA, CMS may waive the consequences of failure to submit a timely-filed NOA. For instance, if a HHA requests a waiver of the payment consequences due to an exceptional circumstance, the home health agency would fully document and furnish any requested documentation to CMS, through their corresponding MAC, for a determination of exception. We are proposing that these exceptional circumstances would be the same as those in place for the hospice NOE. That is, we are proposing that an exceptional circumstance for such waiver would be, but is not limited to the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.
- A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.
- A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to not be under the control of the home health agency.

We are soliciting comments on our proposals to phase-out the split percentage payments beginning in CY 2020 with the elimination of split-percentage payments in CY 2021 for existing HHAs (that is, those HHAs certified to participate in Medicare prior to January 1, 2019). We note that in the CY 2019 HH PPS final rule (83 FR 56463), we finalized that HHAs certified for participation in Medicare on and after January 1, 2019, would not receive split percentage payments beginning in CY 2020. We are also soliciting comments on the implementation of a NOA process, including the NOA timely-filing requirement, for all HHAs, in CY 2021 and subsequent years; and the corresponding regulation text changes at § 484.205.

H. Proposed Regulatory Change To Allow Therapist Assistants To Perform Maintenance Therapy

As referenced in our regulations at § 409.44(c)(2)(iii), in order for therapy visits to be covered in the home health setting one of three criteria must be met: There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition; the unique clinical condition of a patient requires the specialized skills, knowledge, and judgment of a qualified therapist to design or establish a safe and effective maintenance program required in connection with the patient's specific illness or injury; or the unique clinical condition of a patient requires the specialized skills of a qualified therapist to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. The regulations at § 409.44(c)(2)(iii)(C) state that where the clinical condition of the patient is such that the complexity of the therapy services required to maintain function involves the use of complex and sophisticated therapy procedures to be delivered by the therapist himself/herself (and not an assistant) or the clinical condition of the patient is such that the complexity of the therapy services required to maintain function must be delivered by the therapist himself/herself (and not an assistant) in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services shall be covered.

In contrast to restorative therapy, provided when the goals of care are geared towards patient improvement, maintenance therapy is provided when improvement is not feasible in order to prevent or slow further decline/deterioration of the patient's condition. While a therapist assistant is able to perform restorative therapy under the Medicare home health benefit, the regulations at § 409.44(c)(2)(iii)(C) state that only a qualified therapist, and not an assistant, can perform maintenance therapy. Of note, the CY 2011 HH PPS final rule (75 FR 70372) reorganized the text regarding this regulation, but did not re-evaluate the policy.

The regulations at § 484.115(g) and (i) state that qualified occupational and physical therapist assistants are licensed as assistants unless licensure does not apply, are registered or certified, if applicable, as assistants by the state in which practicing, and have graduated from an approved curriculum for therapist assistants, and passed a national examination for therapist assistants. In states where licensure does not apply, therapist assistants must meet certain education and/or proficiency examination requirements. For example, physical therapist assistants (PTAs) in general, practice in accordance with physical therapy state practice acts, providing many of the services that a physical therapist (PT) provides, such as therapeutic exercise, mobilization, and passive manipulation.[15] Services must be commensurate with the PTA's education, training, and experience, and must be under the direction of a supervising PT. Additionally, Medicare allows services furnished by therapist assistants to be included as part of the covered services under a benefit when provided under the direction and supervision of a qualified therapist.[16] The regulations at § 409.44(c) set out the skilled service requirements for physical therapy, speech-language pathology services, and occupational therapy under the home health benefit. In accordance with § 409.44(c)(1)(i), a patient must be under a physician plan of care with documented therapy goals established by a qualified therapist in conjunction with the physician. Additionally, in accordance with § 409.44(c)(2)(i)(A) and (B), the patient's function must be initially assessed and reassessed at least every 30 calendar days by a qualified therapist. As such, under the Medicare home health benefit, a therapist assistant can furnish services covered under a home health plan of care, when provided under the direction and supervision of a qualified therapist, responsible for establishing the plan of care and assessing and reassessing the patient.

[15] *https://www.laptboard.org/index.cfm/rules/practiceact.*

[16] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

While Medicare allows for skilled maintenance therapy in a SNF, HH, and other outpatient settings, the type of clinician that can provide the therapy services vary by setting. In some settings both the therapist and the therapist assistant can deliver the skilled maintenance therapy services, and in other settings, only the therapist can deliver the skilled maintenance therapy services. For example, Medicare regulations allow therapist assistants to provide maintenance therapy in a SNF, but not in the home health setting. Furthermore, commenters on the CY 2019 Physician Fee Schedule final rule (83 FR 59654) noted concerns about shortages of therapists and finalized payment for outpatient therapy services for which payment is made for services that are furnished by a therapist assistant. As such, this rule recognizes that therapist assistants play a valuable role in the provision of needed therapy services.

We believe it would be appropriate to allow therapist assistants to perform maintenance therapy services under a maintenance program established by a qualified therapist under the home health benefit, if acting within the therapy scope of practice defined by state licensure laws. The qualified therapist would still be responsible for the initial assessment; plan of care; maintenance program development and modifications; and reassessment every 30 days, in addition to supervising the services provided by the therapist assistant. We believe this would allow home health agencies more latitude in resource utilization. Furthermore, allowing assistants to perform maintenance therapy would be consistent with other post-acute care settings, including SNFs. Thus, we are proposing to modify the regulations at § 409.44(c)(2)(iii)(C) to allow therapist assistants (rather than only therapists) to perform maintenance therapy under the Medicare home health benefit. We are soliciting comments regarding this proposal and we also welcome feedback on whether this proposal would require therapists to provide more frequent patient reassessment or maintenance program review when the services are being performed by a therapist assistant. We are also soliciting comments on whether we should revise the description of the therapy codes to indicate maintenance services performed by a physical or occupational therapist assistant (G0151 and G0157) versus a qualified therapist, or simply remove the therapy code indicating the establishment or delivery of a safe and effective physical therapy maintenance program, by a physical therapist (G0159). We welcome comments on the importance of tracking whether a visit is for maintenance or restorative therapy or whether it would be appropriate to only identify whether the service is furnished by a qualified therapist or an assistant. Finally, we seek comments on any possible effects on the quality of care that could result by allowing therapist assistants to perform maintenance therapy.

I. Proposed Changes to the Home Health Plan of Care Regulations at § 409.43

As a condition for payment of Medicare home health services, the regulations at § 409.43(a), home health plan of care content requirements, state that the plan of care must contain those items listed in § 484.60(a) that specify the standards relating to a plan of care that an HHA must meet in order to participate in the Medicare program. The home health conditions of participation (CoPs) at § 484.60(a) set forth the content requirements of the individualized home health plan of care. In the January 13, 2017 final rule, ''Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies'' (82 FR 4504), we finalized changes to the plan of care requirements under the home health CoPs by reorganizing the existing plan of care content requirements at § 484.18(a), adding two additional plan of care content requirements, and moving the plan of care content requirements to § 484.60(a). Specifically, in addition to the longstanding plan of care content requirements previously listed at § 484.18(a), a home health plan of care must also include the following:

- A description of the patient's risk for emergency department visits and hospital readmission, and all necessary interventions to address the underlying risk factors; and
- Information related to any advanced directives.

The new content requirements for the plan of care at § 484.60(a) became effective January 13, 2018 (82 FR 31729) and the Interpretive Guidelines to accompany the new CoPs were released on August 31, 2018. Since implementation of the new home health CoP plan of care requirements, we clarified in subregulatory guidance in the Medicare Benefit Policy Manual, chapter 7,[17] that the plan of care must include the identification of the responsible discipline(s) providing home health services, and the frequency and duration of all visits, as well as those items required by the CoPs that establish the need for such services (§ 484.60(a)(2)(iii) and (iv)).

However, the current requirements at § 409.43(a) may be overly prescriptive and may interfere with timely payment for otherwise eligible episodes of care. To mitigate these potential issues, we are proposing to change the regulations text at § 409.43(a). Specifically, we are proposing to change the regulations text to state that for HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment. In addition, the plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in 42 CFR 484.60(a) that establish the need for such services. All care provided must be in accordance with the plan of care. While these newly-added plan of care items at § 484.60(a) remain CoP, we believe that violations for missing required items are best addressed through the survey process, rather than through claims denials for otherwise eligible periods of care. We are soliciting comments on this proposal to change to the regulations text at § 409.43 to state that the home health plan of care must include those items listed in 42 CFR 484.60(a) that establish the need for such services.

IV. Proposed Provisions of the 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) and in the regulations at 42 CFR part 484, subpart F, 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,

[17] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington are required to compete in the Model. 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 based on the competing HHAs' performance on applicable measures. The maximum payment adjustment percentage increases incrementally, upward or downward, over the course of the HHVBP Model in the following manner: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY), which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS), completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.

In the CY 2017 HH PPS final rule (81 FR 76741 through 76752), CY 2018 HH PPS final rule (83 FR 51701 through 51706), and CY 2019 HH PPS final rule (83 FR 56527 through 56547), we finalized changes to the HHVBP Model. Some of those changes included adding and removing measures from the applicable measure set, revising our methodology for calculating benchmarks and achievement thresholds at the state level, creating an appeals process for recalculation requests, and revising our methodologies for weighting measures and assigning improvement points.

B. Public Reporting of Total Performance Scores and Percentile Rankings Under the HHVBP Model

As stated previously and discussed in prior rulemaking, one of the goals of the HHVBP Model is to enhance the current public reporting processes for home health. In the CY 2016 HH PPS final rule, we finalized our proposed reporting framework for the HHVBP Model, including both the annual and quarterly reports that are made available to competing HHAs and a separate, publicly available quality report (80 FR 68663 through 68665). We stated that such publicly available performance reports would inform home health industry stakeholders (consumers, physicians, hospitals) as well as all competing HHAs delivering care to Medicare beneficiaries within selected state boundaries on their level of quality relative to both their peers and their own past performance, and would also provide an opportunity to confirm that the beneficiaries referred for home health services are being provided the best quality of care available. We further stated that we intended to make public competing HHAs' TPSs with the intention of encouraging providers and other stakeholders to utilize quality ranking when selecting an HHA. As summarized in the CY 2016 final rule (80 FR 68665), overall, commenters generally encouraged the transparency of data pertaining to the HHVBP Model. Commenters offered that to the extent possible, accurate comparable data would provide HHAs the ability to improve care delivery and patient outcomes, while better predicting and managing quality performance and payment updates.

We have continued to discuss and solicit comments on the scope of public reporting under the HHVBP Model in subsequent rulemaking. In the CY 2017 final rule (81 FR 76751 through 76752), we discussed the public display of total performance scores, stating that annual publicly available performance reports would be a means of developing greater transparency of Medicare data on quality and aligning the competitive forces within the market to deliver care based on value over volume. We stated our belief that the public reporting of competing HHAs' performance scores under the HHVBP Model would support our continued efforts to empower consumers by providing more information to help them make health care decisions, while also encouraging providers to strive for higher levels of quality. We explained that we have employed a variety of means (CMS Open Door Forums, webinars, a dedicated help desk, and a web-based forum where training and learning resources are regularly posted) to facilitate direct communication, sharing of information and collaboration to ensure that we maintain transparency while developing and implementing the HHVBP Model. This same care was taken with our plans to publicly report performance data, through collaboration with other CMS components that use many of the same quality measures. We also noted that section 1895(b)(3)(B)(v) of the Act requires HHAs to submit patient-level quality of care data using the OASIS and the HHCAHPS, and that section 1895(b)(3)(B)(v)(III) of the Act states that this quality data is to be made available to the public. Thus, HHAs have been required to collect OASIS data since 1999 and report HHCAHPS data since 2012.

We solicited further public comment in the CY 2019 HH PPS proposed rule (83 FR 32438) on which information from the Annual Total Performance Score and Payment Adjustment Report (Annual Report) should be made publicly available. We noted that HHAs have the opportunity to review and appeal their Annual Report 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 Report are 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 would consider what information, specifically from the Annual Report, we may consider proposing for public reporting in future rulemaking.

As we summarized in the CY 2019 HH PPS final rule (83 FR 56546 through 56547), several commenters expressed support for publicly reporting information from the Annual Total Performance Score and Payment Adjustment Report, as they believed it would better inform consumers and allow for more meaningful and objective comparisons among HHAs. Other commenters suggested that CMS consider providing the percentile ranking for HHAs along with their TPS and expressed interest in publicly reporting all information relevant to the HHVBP Model. Several commenters expressed concern with publicly displaying HHAs' TPSs, citing that the methodology is still evolving and pointing out that consumers already have access to data on the quality measures in the Model on Home Health Compare. Another commenter believed that publicly reporting data just for states included in the HHVBP Model could be confusing for consumers.

Our belief remains that publicly reporting HHVBP data would enhance the current home health public reporting processes as it would better inform beneficiaries when choosing an HHA, while incentivizing HHAs to improve quality. Although the data made public would only pertain to the final performance year of the Model, we believe that publicly reporting HHVBP data for Performance Year 5 would nonetheless incentivize HHAs to improve performance. Consistent with our discussion in prior rulemaking of the information that we are considering

for public reporting under the HHVBP Model, we propose to publicly report, on the CMS website the following two points of data from the final CY 2020 (PY) 5 Annual Report for each participating HHA in the Model that qualified for a payment adjustment for CY 2020: (1) The HHA's TPS from PY 5, and (2) the HHA's corresponding PY 5 TPS Percentile Ranking. We are considering making these data available on the HHVBP Model page of the CMS Innovation website (*https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model*). These data would be reported for each such competing HHA by agency name, city, state, and by the agency's CMS Certification Number (CCN). We expect that these data would be made public after December 1, 2021, the date by which we intend to complete the CY 2020 Annual Report appeals process and issuance of the final Annual Report to each HHA.

As discussed in prior rulemaking, we believe the public reporting of such data would further enhance quality reporting under the Model by encouraging participating HHAs to provide better quality of care through focusing on quality improvement efforts that could potentially improve their TPS. In addition, we believe that publicly reporting performance data that indicates overall performance may assist beneficiaries, physicians, discharge planners, and other referral sources in choosing higher-performing HHAs within the nine Model states and allow for more meaningful and objective comparisons among HHAs on their level of quality relative to their peers.

We believe that the TPS would be more meaningful if the corresponding TPS Percentile Ranking were provided so consumers can more easily assess an HHA's relative performance. We would also provide definitions for the HHVBP TPS and the TPS Percentile Ranking methodology to ensure the public understands the relevance of these data points and how they were calculated.

Under our proposal, the data reported would be limited to one year of the Model. We believe this proposal strikes a balance between allowing for public reporting under the Model for the reasons discussed while heeding commenters' concerns about reporting performance data for earlier performance years of the HHVBP Model. We believe publicly reporting the TPS and TPS Percentile Ranking for CY 2020 would enhance quality reporting under the Model by encouraging participating HHAs to provide better quality of care and would promote transparency, and could enable beneficiaries to make better informed decisions about where to receive care.

We are soliciting comment on our proposal to publicly report the Total Performance Score and Total Performance Score Percentile Ranking from the final CY 2020 PY 5 Annual Report for each HHA in the nine Model states that qualified for a payment adjustment for CY 2020. We are also soliciting comment on our proposed amendment to § 484.315 to reflect this policy. Specifically, we are proposing to add new paragraph (d) to specify that CMS will report, for performance year 5, the TPS and the percentile ranking of the TPS for each competing HHA on the CMS website.

C. CMS Proposal To Remove Improvement in Pain Interfering With Activity Measure (NQF #0177)

As discussed in section V.C. of this proposed rule, CMS is proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the Home Health Quality Reporting Program (HH QRP) beginning with CY 2022. Under this proposal, HHAs would no longer be required to submit OASIS Item M1242, Frequency of Pain Interfering with Patient's Activity or Movement, for the purposes of the HH QRP beginning January 1, 2021. As HHAs would continue to be required to submit their data for this measure through CY 2020, we do not anticipate any impact on the collection of this data and the inclusion of the measure in the HHVBP Model's applicable measure set for the final performance year (CY 2020) of the Model.

V. Proposed Updates to the Home Health Care Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of 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 in accordance with this clause, the Secretary shall reduce the home health 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, 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 (except in 2018 and 2020) 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), the CY 2018 HH PPS final rule (82 FR 51711 through 51712), and the CY 2019 HH PPS final rule (83 FR 56547).

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

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). In the CY 2019 HH PPS final rule (83 FR 56548 through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2021 HH QRP

The HH QRP currently includes 19 [18] measures for the CY 2021 program year, as outlined in Table 26.

[18] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

TABLE 26: MEASURES CURRENTLY ADOPTED FOR THE CY 2021 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).
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.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
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).
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.
HHCAHPS-based	
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (NQF #0517) - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

D. Proposed Removal of HH QRP Measures Beginning With the CY 2022 HH QRP

In line with our Meaningful Measures Initiative, we are proposing to remove one measure from the HH QRP beginning with the CY 2022 HH QRP.

1. Proposed Removal of the Improvement in Pain Activity Measure (NQF #0177)

We are removing pain-associated quality measures from its quality reporting programs in an effort to mitigate any potential unintended, over-prescription of opioid medications inadvertently driven by these measures. We are proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP under our measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

In the CY 2007 HH PPS final rule (71 FR 65888 through 65891), we adopted the Improvement in Pain Interfering with Activity Measure beginning with the CY 2007 HH QRP. The measure was NQF-endorsed (NQF #0177) in March 2009. This risk-adjusted outcome measure reports the percentage of HH episodes during which the patient's frequency of pain with activity or movement improved. The measure is calculated using OASIS Item M1242, Frequency of Pain Interfering with Patient's Activity or Movement.[19]

We evaluated the Improvement in Pain Interfering with Activity Measure (NQF #0177) and determined that the measure could have unintended consequences with respect to responsible use of opioids for the management of pain. In 2018, CMS published a comprehensive roadmap, available at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf,* which outlined the agency's efforts to address national issues around prescription opioid misuse and overuse. Because the Medicare program pays for a significant amount of prescription opioids, the roadmap was designed to promote appropriate stewardship of these medications that can provide a medical benefit but also carry a risk for patients, including those receiving home health. One key component of this strategy is to prevent new cases of opioid use disorder, through education, guidance and monitoring of opioid prescriptions. When used correctly, prescription opioids are helpful for treating pain. However, effective non-opioid pain treatments are available to providers and CMS is working to promote their use.

Although we are not aware of any scientific studies that support an association between the prior or current iterations of the Improvement in Pain Interfering with Activity Measure (NQF #0177) and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, we are proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP under measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M1242, Frequency of Pain Interfering with Patient's Activity or Movement for the purposes of this measure beginning January 1, 2021. We are unable to remove M1242 earlier due to the timelines associated with implementing changes to OASIS. If finalized as proposed, data for this

[19] 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-Outcome-Measures-Table-OASIS-D-11-2018c.pdf.*

measure would be publicly reported on HH Compare until April 2020.

We are inviting public comment on this proposal.

E. Proposed New and Modified HH QRP Quality Measures Beginning With the CY 2022 HH QRP

In this proposed rule, we are proposing to adopt two process measures for the HH QRP under section 1895(b)(3)(B)(v)(IV)(aa) of the Act, both of which would satisfy section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the quality measure domain titled ''Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions from a [post-acute care] PAC provider to another applicable setting, including a different PAC provider, a hospital, a critical access hospital, or the home of the individual.'' Given the length of this domain title, hereafter, we will refer to this quality measure domain as ''Transfer of Health Information.'' The two measures we are proposing to adopt are: (1) Transfer of Health Information to Provider–Post-Acute Care; and (2) Transfer of Health Information to Patient–Post-Acute Care. Both of these proposed measures support our Meaningful Measures priority of promoting effective communication and coordination of care, specifically the Meaningful Measure area of the transfer of health information and interoperability. One data element in the Transfer of Health Information to Patient–Post-Acute Care measure evaluates whether information was sent to the patient, family, and caregiver at discharge.

In addition to the two measure proposals, we are proposing to update the specifications for the Discharge to Community–Post Acute Care (PAC) HH QRP measure to exclude baseline nursing facility (NF) residents from the measure.

1. Proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure is a process-based measure that assesses whether or not a current reconciled medication list is given to the admitting provider when a patient is discharged/transferred from his or her current PAC setting.

(a) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency, and 9 percent who were discharged to SNFs.[20] The proportion of patients being discharged from an acute care hospital to a PAC setting was greater among beneficiaries enrolled in Medicare fee-for-service (FFS), underscoring the importance of the measure. Among Medicare FFS patients discharged from an acute hospital, 42 percent went directly to PAC settings. Of that 42 percent, 20 percent were discharged to a SNF, 18 percent were discharged to an HHA, three percent were discharged to an IRF, and one percent were discharged to an LTCH.[21]

The transfer and/or exchange of health information from one provider to another can be done verbally (for example, clinician-to-clinician communication in-person or by telephone), paper-based (for example, faxed or printed copies of records), and via electronic communication (for example, through a health information exchange network using an electronic health/medical record, and/or secure messaging). Health information, such as medication information, that is incomplete or missing increases the likelihood of a patient or resident safety risk, and is often life-threatening.[22] [23] [24] [25] [26] [27] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[28] [29] [30] [31] [32] [33] [34] [35] [36] [37] [38] [39] Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission defines [40] as a patient safety event that results in death, permanent harm, or severe temporary harm. Failed or ineffective patient handoffs are estimated to play a role in 20 percent of serious preventable adverse events.[41] When care transitions

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[31] Institute of Medicine. ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press 2007. Available at: *https://www.nap.edu/read/11623/chapter/1.*

[32] Kitson, N.A., Price, M., Lau, F.Y., & Showler, G., ''Developing a medication communication framework across continuums of care using the Circle of Care Modeling approach,'' BMC Health Services Research, 2013, Vol. 13(1), pp. 1–10.

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[34] Institute of Medicine. ''Preventing medication errors: quality chasm series,'' Washington, DC: The National Academies Press 2007. Available at: *https://www.nap.edu/read/11623/chapter/1.*

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[40] The Joint Commission, ''Sentinel Event Policy'' available at *https://www.jointcommission.org/sentinel_event_policy_and_procedures/.*

[41] The Joint Commission. ''Sentinel Event Data Root Causes by Event Type 2004–2015.'' 2016.

Continued

are enhanced through care coordination activities, such as expedited patient information flow, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[42] [43] [44] [45] [46] [47]

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.[48] [49] The rising incidence of preventable adverse events, complications, and hospital readmissions have drawn attention to the importance of the timely transfer of health information and care preferences at the time of transition. Failures of care coordination, including poor communication of information, were estimated to cost the U.S. health care system between $25 billion and $45 billion in wasteful spending in 2011.[50] The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.[51] [52]

Patients in PAC settings often have complicated medication regimens and require efficient and effective communication and coordination of care between settings, including detailed transfer of medication information.[53] [54] [55] Patients in PAC settings may be vulnerable to adverse health outcomes due to insufficient medication information on the part of their health care providers, and the higher likelihood for multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[56] [57] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[58] For older patients discharged from the hospital, 80 percent of the medication errors occurring during patient handoffs relate to miscommunication between providers [59] and for those transferring to an HHA, medication errors typically relate to transmission of inaccurate discharge medication lists.[60] Medication errors and one-fifth of ADEs occur during transitions between settings, including admission to or discharge from a hospital to home or a PAC setting, or transfer between hospitals.[61] [62]

Patients in PAC settings often take multiple medications. Consequently, PAC providers regularly are in the position of starting complex new medication regimens with little knowledge of the patients or their medication history upon admission. Medication discrepancies in PAC are common, such as those identified in transition from hospital to SNF [63] and hospital to home.[64] In one small intervention study, approximately 90 percent of the sample of 101 patients experienced at least one medication discrepancy in the transition from hospital to home care.[65]

We would define a reconciled medication list as a list of the current prescribed and over the counter (OTC) medications, nutritional supplements,

Available at: *https://www.jointcommission.org/assets/1/23/jconline_Mar_2_2016.pdf.*

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vitamins, and homeopathic and herbal products administered by any route to the patient/resident at the time of discharge or transfer. Medications may also include but are not limited to total parenteral nutrition (TPN) and oxygen. The current medications should include those that are: (1) Active, including those that will be discontinued after discharge; and (2) those held during the stay and planned to be continued/resumed after discharge. If deemed relevant to the patient's/resident's care by the subsequent provider, medications discontinued during the stay may be included.

A reconciled medication list often includes important information about: (1) The patient/resident—including their name, date of birth, information, active diagnoses, known medication and other allergies, and known drug sensitivities and reactions; and (2) each medication, including the name, strength, dose, route of medication administration, frequency or timing, purpose/indication, any special instructions (for example, crush medications), and, for any held medications, the reason for holding the medication and when medication should resume. This information can improve medication safety. Additional information may be applicable and important to include in the medication list such as the patient's/resident's weight and date taken, height and date taken, patient's preferred language, patient's ability to self-administer medication, when the last dose of the medication was administered by the discharging provider, and when the final dose should be administered (for example, end of treatment). This is not an exhaustive list of the information that could be included in the medication list. The suggested elements detailed in the definition above are for guidance purposes only and are not a requirement for the types of information to be included in a reconciled medication list in order to meet the measure criteria.

(b) Stakeholder and TEP Input

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) measure was developed after consideration of feedback we received from stakeholders and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests we conducted in accordance with the CMS Measures Management System Blueprint.

Our measure development contractors convened a TEP, which met on September 27, 2016,[66] January 27, 2017, and August 3, 2017 [67] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened a TEP on April 20, 2018 for the purpose of obtaining expert input on the proposed measure, including the measure's reliability, components of face validity, and the feasibility of implementing the measure across PAC settings. Overall, the TEP was supportive of the measure, affirming that the measure provides an opportunity to improve the transfer of medication information. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4-June 2018'' is available at *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.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS Measures Management System Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. The comments received expressed overall support for the measure. Several commenters suggested ways to improve the measure, primarily related to what types of information should be included at transfer. We incorporated this input into development of the proposed measure. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT—Medication—Profile—Transferred—Public—Comment—Summary— Report'' is available at *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.*

(c) Pilot Testing

The proposed measure was tested between June and August 2018 in a pilot test that involved 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 records. Analysis of agreement between coders within each participating facility (266 qualifying pairs) indicated a 93-percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented across PAC settings. Further, more than half of the sites that participated in the pilot test stated during the debriefing interviews that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report is available at: *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.*

(d) Measure Applications Partnership (MAP) Review and Related Measures

We included the proposed measure on the 2018 Measures Under Consideration (MUC) list for HH QRP. The NQF-convened MAP Post-Acute Care- Long Term Care (PAC LTC) Workgroup met on December 10, 2018 and provided input on this proposed Transfer of Health Information to the Provider–Post-Acute Care measure. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information. The MAP also suggested that CMS consider a measure that can be adapted to capture bi-directional information exchange and recommended that the medication information transferred include important information about supplements and opioids. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Projects/i-m/MAP/PAC-LTC_Workgroup/*

[66] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.*

[67] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2–3-Summary-Report_Final_Feb2018.pdf.*

2019_Considerations_for_Implementing_Measures_Draft_Report.aspx.

As part of the measure development and selection process, we identified one NQF-endorsed quality measure related to the proposed measure, titled Documentation of Current Medications in the Medical Record (NQF #0419e, CMS eCQM ID: CMS68v8). This measure was adopted as one of the recommended adult core clinical quality measures for eligible professionals for the EHR Incentive Program beginning in 2014, and was adopted under the Merit-based Incentive Payment System (MIPS) quality performance category beginning in 2017. The measure is calculated based on the percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all resources immediately available on the date of the encounter. The proposed Transfer of Health Information to the Provider–Post-Acute Care measure addresses the transfer of medication information whereas the NQF-endorsed measure #0419e assesses the documentation of medications, but not the transfer of such information. Further, the proposed measure utilizes standardized patient assessment data elements (SPADEs), which is a requirement for measures specified under the Transfer of Health Information measure domain under section 1899B(c)(1)(E) of the Act, whereas NQF #0419e does not. After review of the NQF-endorsed measure, we determined that the proposed Transfer of Health Information to Provider–Post-Acute Care measure better addresses the Transfer of Health Information measure domain, which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through post-acute care assessment instruments.

Section 1899B(e)(2)(A) of the Act requires that measures specified by the Secretary under section 1899B of the Act be endorsed by the consensus-based entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF endorsed as long as due consideration is given to the measures that have been endorsed or adopted by the consensus-based entity under a contract with the Secretary. For these reasons, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(e) Quality Measure Calculation

The proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) quality measure is calculated as the proportion of quality episodes with a discharge/transfer assessment indicating that a current reconciled medication list was provided to the admitting provider at the time of discharge/transfer.

The proposed measure denominator is the total number of quality episodes ending in discharge/transfer to an ''admitting provider,'' which is defined as: A short-term general hospital, intermediate care, home under care of another organized home health service organization or a hospice, a hospice in an institutional facility, a SNF, an LTCH, an IRF, an inpatient psychiatric facility, or a critical access hospital (CAH). These providers were selected for inclusion in the denominator because they represent admitting providers captured by the current discharge location items on the OASIS. The proposed measure numerator is the number of HH quality episodes (Start of Care or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS Assessment) indicating a current reconciled medication list was provided to the admitting provider at the time of discharge/transfer. The proposed measure also collects data on how information is exchanged in PAC facilities, informing consumers and providers on how information was transferred at discharge/transfer. Data pertaining to how information is transferred by PAC providers to other providers and/or to patients/family/caregivers will provide important information to consumers, improving shared-decision making while selecting PAC providers. For additional technical information about this proposed measure, including information about the measure calculation and the standardized items used to calculate this measure, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available on the website at: *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.* The data source for the proposed quality measure is the OASIS assessment instrument for HH patients.

For more information about the data submission requirements we are proposing for this measure, we refer readers to section V.I.2. of this proposed rule.

2. Proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure

The proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) measure is a process-based measure that assesses whether or not a current reconciled medication list was provided to the patient, family, and/or caregiver when the patient was discharged from a PAC setting to a private home/apartment, a board and care home, assisted living, a group home or transitional living.

(a) Background

In 2013, 22.3 percent of all acute hospital discharges were discharged to PAC settings, including 11 percent who were discharged to home under the care of a home health agency.[68] The communication of health information, such as a reconciled medication list, is critical to ensuring safe and effective patient transitions from health care settings to home and/or other community settings. Incomplete or missing health information, such as medication information, increases the likelihood of a risk to patient safety, often life-threatening.[69] [70] [71] [72] [73] Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher

[68] Tian, W. ''An all-payer view of hospital discharge to postacute care,'' May 2016. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

[69] Kwan, J.L., Lo, L., Sampson, M., & Shojania, K.G., ''Medication reconciliation during transitions of care as a patient safety strategy: a systematic review,'' Annals of Internal Medicine, 2013, Vol. 158(5), pp. 397–403.

[70] Boockvar, K.S., Blum, S., Kugler, A., Livote, E., Mergenhagen, K.A., Nebeker, J.R., & Yeh, J., ''Effect of admission medication reconciliation on adverse drug events from admission medication changes,'' Archives of Internal Medicine, 2011, Vol. 171(9), pp. 860–861.

[71] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R., ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' JAMA, 2011, Vol. 306(8), pp. 840–847.

[72] Basey, A.J., Krska, J., Kennedy, T.D., & Mackridge, A.J., ''Prescribing errors on admission to hospital and their potential impact: a mixed-methods study,'' BMJ Quality & Safety, 2014, Vol. 23(1), pp. 17–25.

[73] Desai, R., Williams, C.E., Greene, S.B., Pierson, S., & Hansen, R.A., ''Medication errors during patient transitions into nursing homes: characteristics and association with patient harm,'' The American Journal of Geriatric Pharmacotherapy, 2011, Vol. 9(6), pp. 413–422.

likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[74] [75] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[76] [77] [78] The efficient and effective communication and coordination of medication information may be critical to prevent potentially deadly adverse events. When care coordination activities enhance care transitions, these activities can reduce duplication of care services and costs of care, resolve conflicting care plans, and prevent medical errors.[79] [80]

Finally, the transfer of a patient's discharge medication information to the patient, family, and/or caregiver is a common practice and supported by discharge planning requirements for participation in Medicare and Medicaid programs.[81] [82] Most PAC EHR systems generate a discharge medication list to promote patient participation in medication management, which has been shown to be potentially useful for improving patient outcomes and transitional care.[83]

(b) Stakeholder and TEP Input

The proposed measure was developed after consideration of feedback we received from stakeholders, and four TEPs convened by our contractors. Further, the proposed measure was developed after evaluation of data collected during two pilot tests, we conducted in accordance with the CMS MMS Blueprint.

Our measure development contractors convened a TEP which met on September 27, 2016,[84] January 27, 2017, and August 3, 2017 [85] to provide input on a prior version of this measure. Based on this input, we updated the measure concept in late 2017 to include the transfer of a specific component of health information—medication information. Our measure development contractors reconvened this TEP on April 20, 2018 to seek expert input on the measure. Overall, the TEP members supported the proposed measure, affirming that the measure provides an opportunity to improve the transfer of medication information. Most of the TEP members believed that the measure could improve the transfer of medication information to patients, families, and caregivers. Several TEP members emphasized the importance of transferring information to patients and their caregivers in a clear manner using plain language. A summary of the April 20, 2018 TEP proceedings titled ''Transfer of Health Information TEP Meeting 4—June 2018'' is available at *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.*

Our measure development contractors solicited stakeholder feedback on the proposed measure by requesting comment on the CMS MMS Blueprint website, and accepted comments that were submitted from March 19, 2018 to May 3, 2018. Several commenters noted the importance of ensuring that the instruction provided to patients and caregivers is clear and understandable to promote transparent access to medical record information and meet the goals of the IMPACT Act. The summary report for the March 19 to May 3, 2018 public comment period titled ''IMPACT— Medication Profile Transferred Public Comment Summary Report'' is available at *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.*

(c) Pilot Testing

Between June and August 2018, we held a pilot test involving 24 PAC facilities/agencies, including five IRFs, six SNFs, six LTCHs, and seven HHAs. The 24 pilot sites submitted a total of 801 assessments. Analysis of agreement between coders within each participating facility (241 qualifying pairs) indicated 87 percent agreement for this measure. Overall, pilot testing enabled us to verify its reliability, components of face validity, and feasibility of being implemented the proposed measure across PAC settings. Further, more than half of the sites that participated in the pilot test stated, during debriefing interviews, that the measure could distinguish facilities or agencies with higher quality medication information transfer from those with lower quality medication information transfer at discharge. The pilot test summary report is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-*

[74] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R. ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' Journal of the American Geriatrics Society, 2016, Vol. 64(11), pp. e166–e170.

[75] Chhabra, P.T., Rattinger, G.B., Dutcher, S.K., Hare, M.E., Parsons, K.L., & Zuckerman, I.H., ''Medication reconciliation during the transition to and from long-term care settings: a systematic review,'' Res Social Adm Pharm, 2012, Vol. 8(1), pp. 60–75.

[76] Brody, A.A., Gibson, B., Tresner-Kirsch, D., Kramer, H., Thraen, I., Coarr, M.E., & Rupper, R. ''High prevalence of medication discrepancies between home health referrals and Centers for Medicare and Medicaid Services home health certification and plan of care and their potential to affect safety of vulnerable elderly adults,'' Journal of the American Geriatrics Society, 2016, Vol. 64(11), pp. e166–e170.

[77] Bell, C.M., Brener, S.S., Gunraj, N., Huo, C., Bierman, A.S., Scales, D.C., & Urbach, D.R., ''Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases,'' JAMA, 2011, Vol. 306(8), pp. 840–847.

[78] Sheehan, O.C., Kharrazi, H., Carl, K.J., Leff, B., Wolff, J.L., Roth, D.L., Gabbard, J., & Boyd, C.M., ''Helping older adults improve their medication experience (HOME) by addressing medication regimen complexity in home healthcare,'' Home Healthcare Now. 2018, Vol. 36(1) pp. 10–19.

[79] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., ''The revolving door of rehospitalization from skilled nursing facilities,'' Health Affairs, 2010, Vol. 29(1), pp. 57–64.

[80] Starmer, A.J., Sectish, T.C., Simon, D.W., Keohane, C., McSweeney, M.E., Chung, E.Y., Yoon, C.S., Lipsitz, S.R., Wassner, A.J., Harper, M.B., & Landrigan, C.P., ''Rates of medical errors and preventable adverse events among hospitalized children following implementation of a resident handoff bundle,'' JAMA, 2013, Vol. 310(21), pp. 2262–2270.

[81] CMS, ''Revision to state operations manual (SOM), Hospital Appendix A—Interpretive Guidelines for 42 CFR 482.43, Discharge Planning'' May 17, 2013. Available at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf.*

[82] The State Operations Manual Guidance to Surveyors for Long Term Care Facilities (Guidance § 483.21(c)(1) Rev. 11–22–17) for discharge planning process. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.*

[83] Toles, M., Colon-Emeric, C., Naylor, M.D., Asafu-Adjei, J., Hanson, L.C., ''Connect-home: transitional care of skilled nursing facility patients and their caregivers,'' Am Geriatr Soc., 2017, Vol. 65(10), pp. 2322–2328.

[84] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP_Summary_Report_Final-June-2017.pdf.*

[85] Technical Expert Panel Summary Report: Development of two quality measures to satisfy the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) Domain of Transfer of health Information and Care Preferences When an Individual Transitions to Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Home Health Agencies (HHAs). Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meetings-2-3-Summary-Report_Final_Feb2018.pdf.*

Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html. The summary report for pilot testing conducted in 2017 of a previous version of the data element, at that time intended for benchmarking purposes only, is available at: *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.*

(d) Measure Applications Partnership (MAP) Review and Related Measures

This measure was submitted to the 2018 MUC list for HH QRP. The NQF-convened MAP PAC–LTC Workgroup met on December 10, 2018 and provided input on the use of the proposed Transfer of Health Information to the Patient–Post Acute-Care measure. The MAP conditionally supported this measure pending NQF endorsement, noting that the measure can promote the transfer of important medication information to the patient. The MAP recommended that providers transmit medication information to patients that is easy to understand because health literacy can impact a person's ability to take medication as directed. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Projects/i-m/MAP/PAC-LTC_Workgroup/2019_Considerations_for_Implementing_Measures_Draft_Report.aspx.*

Section 1899B(e)(2)(A) of the Act requires that measures specified by the Secretary under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the NQF. However, when a feasible and practical measure has not been NQF-endorsed for a specified area or medical topic determined appropriate by the Secretary, section 1899B(e)(2)(B) of the Act allows the Secretary to specify a measure that is not NQF-endorsed as long as due consideration is given to the measures that have been endorsed or adopted by the consensus organization identified by the Secretary. Therefore, in the absence of any NQF-endorsed measures that address the proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC), which requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the post-acute care assessment instruments, we believe that there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act. However, we note that we intend to submit the proposed measure to the NQF for consideration of endorsement when feasible.

(e) Quality Measure Calculation

The calculation of the proposed Transfer of Health Information to Patient–Post-Acute Care measure would be based on the proportion of quality episodes with a discharge assessment indicating that a current reconciled medication list was provided to the patient, family, and/or caregiver at the time of discharge.

The proposed measure denominator is the total number of HH quality episodes ending in discharge to a private home/apartment without any further services, a board and care home, assisted living, a group home or transitional living. These health care providers and settings were selected for inclusion in the denominator because they represent discharge locations captured by items on the OASIS. The proposed measure numerator is the number of HH quality episodes with an OASIS discharge assessment indicating a current reconciled medication list was provided to the patient, family, and/or caregiver at the time of discharge. We believe that data pertaining to how information is transferred by PAC providers to other providers and/or to patients/family/caregivers will provide important information to consumers, improving shared-decision making while selecting PAC providers. For technical information about this proposed measure including information about the measure calculation, we refer readers to the document titled ''Proposed Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *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*

For more information about the data submission requirements we are proposing for this measure, we refer readers to section V.I.2. of this proposed rule.

3. Proposed Update to the Discharge to Community (DTC)—Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) Measure

We are proposing to update the specifications for the DTC—PAC HH QRP measure to exclude baseline nursing facility (NF) residents from the measure. This proposed measure exclusion aligns with the proposed updates to measure exclusions for the DTC–PAC measures utilized in quality reporting programs for other PAC providers, as outlined in the FY2020 PPS proposed rules for IRFs and SNFs as well as for LTCHs in the FY2020 IPPS/LTCH PPS proposed rule. This measure assesses successful discharge to the community from an HHA, with successful discharge to the community including no unplanned re-hospitalizations and no death in the 31 days following discharge. We adopted this measure in the CY 2017 HH PPS final rule (81 FR 76765 through 76770).

The DTC–PAC HH QRP measure does not currently exclude baseline NF residents. We have now developed a methodology to identify and exclude baseline NF residents using the Minimum Data Set (MDS) and have conducted additional measure testing work. To identify baseline NF residents, we examine any historical MDS data in the 180 days preceding the qualifying prior acute care admission and index HH episode of care start date. Presence of an OBRA (Omnibus Budget Reconciliation Act)-only assessment (not a SNF PPS assessment) with no intervening community discharge between the OBRA assessment and acute care admission date flags the index HH episode of care as baseline NF resident. We assessed the impact of the baseline NF resident exclusion on HH patient- and agency-level discharge to community rates using CY 2016 and CY 2017 Medicare FFS claims data. Baseline NF residents represented 0.13 percent of the measure population after all measure exclusions were applied. The national observed patient-level discharge to community rate was 78.05 percent when baseline NF residents were included in the measure, increasing to 78.08 percent when they were excluded from the measure. After excluding baseline NF residents to align with current or proposed exclusions in other PAC settings, the agency-level risk-standardized discharge to community rate ranged from 3.21 percent to 100 percent, with a mean of 77.39 percent and standard deviation of 17.27 percentage points, demonstrating a performance gap in this domain. That is, the results show that there is a wide range in measure results, emphasizing the opportunity for providers to improve their measure performance.

Accordingly, we are proposing to exclude baseline NF residents from the DTC–PAC HH QRP measure beginning with the CY 2021 HH QRP. We are proposing to define ''baseline NF residents'' for purposes of this measure as HH patients who had a long-term NF stay in the 180 days preceding their hospitalization and HH episode, with no

intervening community discharge between the NF stay and qualifying hospitalization. We are currently using MDS assessments, which are required quarterly for NF residents, to identify baseline NF residents. A 180-day lookback period ensures that we will capture both quarterly OBRA assessments identifying NF residency and any discharge assessments to determine if there was a discharge to community from NF.

For additional technical information regarding the DTC–PAC HH QRP measure, including technical information about the proposed exclusion, we refer readers to the document titled ''Proposed Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at *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.*

F. HH QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures, standardized patient assessment data elements (SPADEs), and measure concepts under consideration listed in the Table 27 for future years in the HH QRP.

TABLE 27: FUTURE MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS (SPADEs) UNDER CONSIDERATION FOR THE HH QRP

Quality Measures and Measure Concepts
Potentially-preventable hospitalizations
Functional improvement and maintenance outcomes
Opioid use and frequency
Exchange of electronic health information and interoperability
Standardized Patient Assessment Data Elements (SPADEs)
Cognitive complexity, such as executive function and memory
Dementia
Bladder and bowel continence including appliance use and episodes of incontinence
Care preferences, advance care directives, and goals of care
Caregiver Status
Veteran Status
Health disparities and risk factors, including education, sex and gender identity, and sexual orientation

While we will not be responding to comment submissions in response to this Request for Information in the CY 2020 HH PPS final rule, nor will we be finalizing any of these measures, measure concepts, and SPADEs under consideration for the HH QRP in this CY 2020 HH PPS final rule, we intend to use this input to inform our future measure and SPADE development efforts.

G. Proposed Standardized Patient Assessment Data Reporting Beginning With the CY 2022 HH QRP

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that, for CY 2019 (beginning January 1, 2019) and each subsequent year, HHAs report standardized patient assessment data required under section 1899B(b)(1) of the Act. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including HHAs, to submit SPADEs under the Medicare program. Section 1899B(b)(1)(A) of the Act requires that PAC providers must submit SPADEs under applicable reporting provisions, (which for HHAs is the HH QRP) with respect to the admissions and discharges of an individual (and more frequently as the Secretary deems appropriate), and section 1899B(b)(1)(B) defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow; and (6) other categories deemed necessary and appropriate by the Secretary.

In the CY 2018 HH PPS proposed rule (82 FR 35355 through 35371), we proposed to adopt SPADEs that would satisfy the first five categories. While many commenters expressed support for our adoption of SPADEs, including support for our broader standardization goal and support for the clinical usefulness of specific proposed SPADEs in general, we did not finalize the majority of our SPADE proposals in recognition of the concern raised by many commenters that we were moving too fast to adopt the SPADEs and modify our assessment instruments in light of all of the other requirements we were also adopting under the IMPACT Act at that time (82 FR 51737 through 51740). In addition, we noted our intention to conduct extensive testing to ensure that the standardized patient assessment data elements we select are reliable, valid, and appropriate for their intended use (82 FR 51732 through 51733).

However, we did, finalize the adoption of SPADEs for two of the categories described in section 1899B(b)(1)(B) of the Act: (1) Functional status: Data elements currently reported

by HHAs to calculate the measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) along with the additional data elements in Section GG: Functional Abilities and Goals; and (2) Medical conditions and comorbidities: The data elements used to calculate the pressure ulcer measures, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and the replacement measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. We stated that these data elements were important for care planning, known to be valid and reliable, and already being reported by HHAs for the calculation of quality measures (82 FR 51733 through 51735).

Since we issued the CY 2018 HH PPS final rule, HHAs have had an opportunity to familiarize themselves with other new reporting requirements that we have adopted under the IMPACT Act. We have also conducted further testing of the proposed SPADEs, as described more fully elsewhere in this proposed rule, and believe that this testing supports their use in our PAC assessment instruments. Therefore, we are now proposing to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

We are proposing that HHAs would be required to report these SPADEs beginning with the CY 2022 HH QRP. If finalized as proposed, HHAs would be required to report this data with respect to admissions and discharges that occur between January 1, 2021 and June 30, 2021 for the CY 2022 HH QRP. Beginning with the CY 2023 HH QRP, we propose that HHAs must report data with respect to admissions and discharges that occur the successive calendar year (for example, data from FY 2021 for the CY 2023 HH QRP and data from FY 2022 for the CY 2024 HH QRP). For the purposes of the HH QRP, we are proposing that HHAs must submit SPADEs with respect to start of care (SOC), resumption of care (ROC), and discharge with the exception of Hearing, Vision, Race, and Ethnicity SPADEs, which will only be collected with respect to SOC. We are proposing to use SOC for purposes of admissions because, in the HH setting, the start of care is functionally the same as an admission.

We are proposing that HHAs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to SOC only will be deemed to have submitted those SPADEs with respect to both admission and discharge, because it is unlikely that the assessment of those SPADEs at admission will differ from the assessment of the same SPADEs at discharge.

We considered the burden of assessment-based data collection and aimed to minimize additional burden by evaluating whether any data that is currently collected through one or more PAC assessment instruments could be collected as SPADE. In selecting the proposed SPADEs in this proposed rule, we also took into consideration the following factors with respect to each data element:

- Overall clinical relevance;
- Interoperable exchange to facilitate care coordination during transitions in care;
- Ability to capture medical complexity and risk factors that can inform both payment and quality;
- Scientific reliability and validity, general consensus agreement for its usability.

In identifying the SPADEs proposed, we additionally drew on input from several sources, including TEPs, public input, and the results of a recent National Beta Test of candidate data elements conducted by our data element (hereafter ''National Beta Test''), contractor.

The National Beta Test collected data from 3,121 patients and residents across 143 LTCHs, SNFs, IRFs, and HHAs from November 2017 to August 2018 to evaluate the feasibility, reliability, and validity of candidate data elements across PAC settings. The National Beta Test also gathered feedback on the candidate data elements from staff who administered the test protocol in order to understand usability and workflow of the candidate data elements. More information on the methods, analysis plan, and results for the National Beta Test can be found in the document titled, ''Development and Evaluation of Candidate Standardized Patient Assessment Data Elements: Findings from the National Beta Test (Volume 2),'' available at: *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.*

Further, to inform the proposed SPADEs, we took into account feedback from stakeholders, as well as from technical and clinical experts, including feedback on whether the candidate data elements would support the factors described previously. Where relevant, we also took into account the results of the Post-Acute Care Payment Reform Demonstration (PAC PRD) that took place from 2006 to 2012.

H. Proposed Standardized Patient Assessment Data by Category

1. Cognitive Function and Mental Status Data

A number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression, can affect cognitive function and mental status in PAC patient and resident populations.[86] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[87] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[88] [89] [90] and promising treatments for severe traumatic brain injury are currently being tested.[91] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[92] [93] [94] [95] and targeted

[86] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from: *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[87] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[88] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

[89] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[90] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[91] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[92] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: A summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[93] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[94] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: Which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[95] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression

services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[96]

In alignment with our Meaningful Measures Initiative, accurate assessment of cognitive function and mental status of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting effective communication and coordination of care. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient's or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. SPADEs will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable SPADEs assessing cognitive function and mental status are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events. We describe each of the proposed cognitive function and mental status data SPADEs elsewhere in the proposed rule.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status.

a. Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the BIMS meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35356 through 35357), dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[97] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[98]

The BIMS is a performance-based cognitive assessment screening tool that assesses repetition, recall with and without prompting, and temporal orientation. The data elements that make up the BIMS are seven questions on the repetition of three words, temporal orientation, and recall that result in a cognitive function score. The BIMS was developed to be a brief objective screening tool with a focus on learning and memory. As a brief screener, the BIMS was not designed to diagnose dementia or cognitive impairment, but rather to be a relatively quick and easy to score assessment that could identify cognitively impaired patients as well as those who may be at risk for cognitive decline and require further assessment. It is currently in use in two of the PAC assessments: The MDS in SNFs and the IRF–PAI used by IRFs. For more information on the BIMS, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The data elements that comprise the BIMS were first proposed as SPADEs in the CY 2018 HH PPS proposed rule (82 FR 35356 through 35357). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. We also stated that those commenters had noted that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, we received public comments in support of the use of the BIMS in the HH setting. However, a commenter suggested the BIMS should be administered with respect to both admission and discharge, and another commenter encouraged its use at follow-up assessments. Another commenter expressed support for the BIMS to assess significant cognitive impairment, but a few commenters suggested alternative cognitive assessments as more appropriate for the HH settings, such as assessments that would capture mild cognitive impairment and ''functional cognition.''

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the BIMS was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the BIMS to be feasible and reliable for use with PAC patients and residents. More information about the performance of the BIMS in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the BIMS, and the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP

in nursing homes: Practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[96] Crespy SD, Van Haitsma K, Kleban M, Hann CJ. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

[97] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[98] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Some commenters expressed concern that the BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including mild cognitive impairment (MCI). A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

We understand the concerns raised by stakeholders that BIMS, if used alone, may not be sensitive enough to capture the range of cognitive impairments, including functional cognition and MCI, but note that the purpose of the BIMS data elements as SPADEs is to screen for cognitive impairment in a broad population. We also acknowledge that further cognitive tests may be required based on a patient's condition and will take this feedback into consideration in the development of future standardized assessment data elements. However, taking together the importance of assessing cognitive status, stakeholder input, and strong test results, we are proposing that the BIMS data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the BIMS as standardized patient assessment data for use in the HH QRP.

b. Confusion Assessment Method (CAM)

In this proposed rule, we are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35357), the CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether a patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[99] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is a patient assessment instrument that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. The CAM is currently in use in two of the PAC assessments: A four-item version of the CAM is used in the MDS in SNFs, and a six-item version of the CAM is used in the LTCH CARE Data Set (LCDS) in LTCHs. We are proposing the four-item version of the CAM that assesses acute change in mental status, inattention, disorganized thinking, and altered level of consciousness. For more information on the CAM, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The data elements that comprise the CAM were first proposed as SPADEs in the CY 2018 HH PPS proposed rule (82 FR 35357). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on the CAM from August 12 to September 12, 2016 expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination and, therefore, contribute to quality improvement. We also stated that those commenters had noted the CAM is particularly helpful in distinguishing delirium and reversible confusion from other types of cognitive impairment. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at: *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the CAM to assess significant cognitive impairment but noted that functional cognition should also be assessed. Another commenter suggested the CAM was not suitable for the HH setting and noted that the additional cognition items would be redundant with existing assessment items in the OASIS data set.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the CAM was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the CAM to be feasible and reliable for use with PAC patients and residents. More information about the performance of the CAM in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018, although they did not specifically discuss the CAM data elements, the TEP supported the assessment of patient or resident cognitive status with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of

[99] Fick, D.M., Steis, M.R., Waller, J.L., & Inouye, S.K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' *J of Hospital Med* 8(9): 500–505.

stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing delirium, stakeholder input, and strong test results, we are proposing that the CAM data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt CAM as standardized patient assessment data for use in the HH QRP.

c. Patient Health Questionnaire–2 to 9 (PHQ–2 to 9)

We are proposing that the Patient Health Questionnaire–2 to 9 (PHQ–2 to 9) data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements are based on the PHQ–2 mood interview, which focuses on only the two cardinal symptoms of depression, and the longer PHQ–9 mood interview, which assesses presence and frequency of nine signs and symptoms of depression. The name of the data element, the PHQ–2 to 9, refers to an embedded skip pattern that transitions patients with a threshold level of symptoms in the PHQ–2 to the longer assessment of the PHQ–9. The skip pattern is described elsewhere in this proposed rule.

As described in the CY 2018 HH PPS proposed rule (82 FR 35358 through 35359), depression is a common and under-recognized mental health condition. Assessments of depression help PAC providers better understand the needs of their patients and residents by: Prompting further evaluation after establishing a diagnosis of depression; elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge.

The proposed PHQ–2 to 9 is based on the PHQ–9 mood interview. The PHQ–2 consists of questions about only the first two symptoms addressed in the PHQ–9: Depressed mood and anhedonia (inability to feel pleasure), which are the cardinal symptoms of depression. The PHQ–2 has performed well as both a screening tool for identifying depression, to assess depression severity, and to monitor patient mood over time.[100] [101] If a patient demonstrates signs of depressed mood and anhedonia under the PHQ–2, then the patient is administered the lengthier PHQ–9. This skip pattern (also referred to as a gateway) is designed to reduce the length of the interview assessment for patients who fail to report the cardinal symptoms of depression. The design of the PHQ–2 to 9 reduces the burden that would be associated with the full PHQ–9, while ensuring that patients with indications of depressive symptoms based on the PHQ–2 receive the longer assessment.

Components of the proposed data elements are currently used in the OASIS for HHAs (PHQ–2) and the MDS for SNFs (PHQ–9). We are proposing to add the additional data elements of the PHQ–9 to the OASIS to replace M1730, Depression Screening. We are proposing to alter the administration instructions for the existing and new data elements to adopt the PHQ–2 to 9 gateway logic, meaning that administration of the full PHQ–9 is contingent on patient responses to questions about the cardinal symptoms of depression. For more information on the PHQ–2 to 9, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The PHQ–2 data elements were first proposed as SPADEs in the CY 2018 HH proposed rule (82 FR 35358 through 35359). In that proposed rule, we stated that the proposal was informed by input we received from the TEP convened by our data element contractor on April 6 and 7, 2016. The TEP members particularly noted that the brevity of the PHQ–2 made it feasible to administer with low burden for both assessors and PAC patients or residents. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at: *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.*

That rule proposal was also informed by public input that we received through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted from August 12 to September 12, 2016 on three versions of the PHQ depression screener: The PHQ–2; the PHQ–9; and the PHQ–2 to 9 with the skip pattern design. Many commenters were supportive of the standardized assessment of mood in PAC settings, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 while still potentially reducing burden on most patients and residents, as well as test administrators, and ensuring the administration of the PHQ–9, which exhibits higher specificity,[102] for patients and residents who showed signs and symptoms of depression on the PHQ–2. A summary report for to the September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, we received public comments in support of the PHQ–2, with a few commenters noting the limitation that the PHQ–2 is not appropriate for patients who are physically or cognitively impaired.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the PHQ–2 to 9 data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the PHQ–2 to 9 to be feasible and reliable for use with PAC patients and residents. More

[100] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). ''Validity of the Patient Health Questionnaire 2 (PHQ–2) in identifying major depression in older people.'' *J of the A Geriatrics Society,* 55(4): 596–602.

[101] Löwe, B., Kroenke, K., & Gräfe, K. (2005). ''Detecting and monitoring depression with a two-item questionnaire (PHQ–2).'' *J of Psychosomatic Research,* 58(2): 163–171.

[102] Arroll B, Goodyear-Smith F, Crengle S. Gunn J. Kerse N. Fishman T. et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010; 8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

information about the performance of the PHQ–2 to 9 in the National Beta Test can be found in the document titled, ''Proposed Specifications for CY 2020 HH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018, for the purpose of soliciting input on the PHQ–2 to 9. The TEP was supportive of the PHQ–2 to 9 data element set as a screener for signs and symptoms of depression. The TEP's discussion noted that symptoms evaluated by the full PHQ–9 (for example, concentration, sleep, appetite) had relevance to care planning and the overall well-being of the patient or resident, but that the gateway approach of the PHQ–2 to 9 would be appropriate as a depression screening assessment, as it depends on the well-validated PHQ–2 and focuses on the cardinal symptoms of depression. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing depression, stakeholder input, and strong test results, we are proposing that the PHQ–2 to 9 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act and to adopt the PHQ–2 to 9 data elements as standardized patient assessment data for use in the HH QRP.

2. Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. In alignment with our Meaningful Measures Initiative, accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers is expected to make care safer by reducing harm caused in the delivery of care; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting effective communication and coordination of care.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events. We provide rationale and further support for each of the proposed data elements and in the document titled, ''Proposed Specifications for CY 2020 HH QRP Quality Measures and Standardized Patient Assessment Data Elements,'' available at: *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.*

A TEP convened by our data element contractor provided input on the data elements for special services, treatments, and interventions. In a meeting held on January 5 and 6, 2017, the TEP found that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform to common workflow for PAC providers. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *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.*

Comments on the category of special services, treatments, and interventions were also submitted by stakeholders during the CY 2018 HH PPS proposed rule (82 FR 35359 through 35369) public comment period. A few commenters expressed support for the special services, treatments, and interventions data elements but requested that a vendor be contracted to support OASIS questions and answers. A commenter noted that many of these data elements were redundant with current assessment items and encouraged CMS to eliminate the redundancy by removing items similar to the proposed data elements. Another commenter noted that collecting these data elements on patients that come to the HH setting from non-affiliated entities can be challenging. The Medicare Payment Advisory Commission supported the addition of data elements related to specific services, treatments, and interventions, but cautioned that such data elements, when used for risk adjustment, may be susceptible to inappropriate manipulation by providers and expressed that CMS may want to consider requiring a physician signature to attest that the reported service was reasonable and necessary. CMS is not proposing to require a physician signature because the existing Conditions of Participation for HHAs

already require accurate reporting of patient assessment data, and a physician signature would be redundant. We reported this comment in order to accurately represent the public comments received on these proposals in the CY 2017 HH PPS proposed rule.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

a. Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35359 through 35360), chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV but can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy is administered either peripherally or more commonly given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use. The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) for IV chemotherapy require significant resources.

The Chemotherapy (IV, Oral, Other) data element consists of a principal data element (Chemotherapy) and three response option sub-elements: IV chemotherapy, which is generally resource-intensive; Oral chemotherapy, which is less invasive and generally requires less intensive administration protocols; and a third category, Other, provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to chemotherapy delivery by other routes (for example, intraventricular or intrathecal). If the assessor indicates that the patient is receiving chemotherapy on the principal Chemotherapy data element, the assessor would then indicate by which route or routes (IV, Oral, Other) the chemotherapy is administered.

A single Chemotherapy data element that does not include the proposed three sub-elements is currently in use in the MDS in SNFs. For more information on the Chemotherapy (IV, Oral, Other) data element, we refer readers to the document titled ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The Chemotherapy data element was first proposed as a SPADE in the CY 2018 HH PPS proposed rule (82 FR 35359 through 35360). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the IV Chemotherapy data element and suggested it be included as standardized patient assessment data. We also stated that those commenters had noted that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Chemotherapy data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Chemotherapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Chemotherapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Chemotherapy data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the special services, treatments, and interventions. Although the TEP members did not specifically discuss the Chemotherapy data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting

and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing chemotherapy, stakeholder input, and strong test results, we are proposing that the Chemotherapy (IV, Oral, Other) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data for use in the HH QRP.

b. Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35360), radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The proposed data element consists of the single Radiation data element. The Radiation data element is currently in use in the MDS for SNFs. For more information on the Radiation data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The Radiation data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35360). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the Radiation data element, noting its importance and clinical usefulness for patients and residents in PAC settings, due to the side effects and consequences of radiation treatment on patients and residents that need to be considered in care planning and care transitions, the feasibility of the item, and the potential for it to improve quality. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Radiation data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Radiation data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Radiation data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Radiation data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP members did not specifically discuss the Radiation data element, the TEP members supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing radiation, stakeholder input, and strong test results, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Radiation data element as standardized patient assessment data for use in the HH QRP.

c. Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System)

We are proposing that the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35360 through 35361), we proposed a data element

related to oxygen therapy. Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). The data element proposed here capture patient or resident use of three types of oxygen therapy (intermittent, continuous, and high-concentration oxygen delivery system), which reflects the intensity of care needed, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data element, Oxygen Therapy, consists of the principal Oxygen Therapy data element and three sub-elements: Continuous (whether the oxygen was delivered continuously, typically defined as > =14 hours per day); Intermittent; or High-concentration oxygen delivery system. Based on public comments and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we added a third sub-element, high-concentration oxygen delivery system, to the sub-elements, which previously included only intermittent and continuous. If the assessor indicates that the patient is receiving oxygen therapy on the principal oxygen therapy data element, the assessor would then indicate the type of oxygen the patient receives (for example, Continuous, Intermittent, High-concentration oxygen delivery system).

These three proposed sub-elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS for SNFs (''Oxygen Therapy''), previously used in the OASIS–C2 for HHAs (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 > 40 percent''). For more information on the proposed Oxygen Therapy (Continuous, Intermittent, High-concentration oxygen delivery system) data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

The Oxygen Therapy (Continuous, Intermittent) data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35360 through 35361). In that proposed rule, we stated that the proposal was informed by input we received on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Oxygen Therapy (Continuous, Intermittent) data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Oxygen Therapy data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Oxygen Therapy data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Oxygen Therapy data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018, although the TEP did not specifically discuss the Oxygen Therapy data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing oxygen therapy, stakeholder input, and strong test results, we are proposing that the Oxygen Therapy (Continuous, Intermittent, High-Concentration Oxygen Delivery System) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Oxygen (Continuous, Intermittent, High-Concentration Oxygen Delivery System) data element as standardized patient assessment data for use in the HH QRP.

d. Respiratory Treatment: Suctioning (Scheduled, As Needed)

We are proposing that the Suctioning (Scheduled, As needed) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35361 through

35362), suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' or residents' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients and residents with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions, or can be done as needed when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource intensive. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death, or complications associated with hypoxia.

The Suctioning (Scheduled, As needed) data element consists of the principal data element, and two sub-elements: Scheduled and As needed. These sub-elements capture two types of suctioning. Scheduled indicates suctioning based on a specific frequency, such as every hour; as needed means suctioning only when indicated. If the assessor indicates that the patient is receiving suctioning on the principal Suctioning data element, the assessor would then indicate the frequency (Scheduled, As needed). The proposed data element is based on an item currently in use in the MDS in SNFs which does not include our proposed two sub-elements, as well as data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients and residents with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every __ hours]''). For more information on the Suctioning data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

The Suctioning data element was first proposed as standardized patient assessment data elements in the CY 2018 HH PPS proposed rule (82 FR 35361 through 35362). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted from August 12 to September 12, 2016 expressed support for the Suctioning data element currently used in the MDS in SNFs. The input noted the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also stated that those commenters had suggested that we examine the frequency of suctioning to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (Scheduled and As needed) to the suctioning element. The proposed Suctioning data element includes both the principal Suctioning data element that is included on the MDS in SNFs and two sub-elements, Scheduled and As needed. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Suctioning data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Suctioning data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Suctioning data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Suctioning data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Suctioning data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicited additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at *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.*

Taking together the importance of assessing suctioning, stakeholder input, and strong test results, we are proposing that the Suctioning (Scheduled, As needed) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to

adopt the Suctioning (Scheduled, As needed) data element as standardized patient assessment data for use in the HH QRP.

e. Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35362), a tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or if the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such as device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula is also a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element consists of the single Tracheostomy Care data element. The proposed data element is currently in use in the MDS for SNFs (''Tracheostomy care''). For more information on the Tracheostomy Care data element, we refer readers to the document titled ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

The Tracheostomy Care data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35362). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on the Tracheostomy Care data element from August 12 to September 12, 2016 supported this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Tracheostomy Care data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Tracheostomy Care data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Tracheostomy Care data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Tracheostomy Care data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Tracheostomy Care data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing tracheostomy care, stakeholder input, and strong test results, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Tracheostomy Care data element as standardized patient assessment data for use in the HH QRP.

f. Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35362 through 35363), BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (BiPAP) or through a mask continuously (CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident

who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

The proposed data element, Non-invasive Mechanical Ventilator (BIPAP, CPAP), consists of the principal Non-invasive Mechanical Ventilator data element and two response option sub-elements: BiPAP and CPAP. If the assessor indicates that the patient is receiving non-invasive mechanical ventilation on the principal Non-invasive Mechanical Ventilator data element, the assessor would then indicate which type (BIPAP, CPAP). Data elements that assess non-invasive mechanical ventilation are currently included on LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS for the SNF setting (''Non-invasive Mechanical Ventilator (BiPAP/CPAP)''). For more information on the Non-invasive Mechanical Ventilator data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

The Non-invasive Mechanical Ventilator data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35362 through 35363). In that proposed rule, we stated that the proposal was informed by input we received from August 12 to September 12, 2016 on a single data element, BiPAP/CPAP, that captures equivalent clinical information but uses a different label than the data element currently used in the MDS in SNFs and LCDS in LTCHs, expressing support for this data element, noting the feasibility of these items in PAC, and the relevance of this data element for facilitating care coordination and supporting care transitions. In addition, we also stated that some commenters supported separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Non-invasive Mechanical Ventilator data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Non-invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Non-invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Non-invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Non-invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing non-invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data for use in the HH QRP.

g. Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35363 through 35364), invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[103]

The proposed data element, Invasive Mechanical Ventilator, consists of a

[103] Wunsch, H., Linde-Zwirble, W.T., Angus, D.C., Hartman, M.E., Milbrandt, E.B., & Kahn, J.M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' *Critical Care Med* 38(10): 1947–1953.

single data element. Data elements that capture invasive mechanical ventilation are currently in use in the MDS in SNFs and LCDS in LTCHs. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

The Invasive Mechanical Ventilator data element was first proposed as a SPADE in the CY 2018 HH PPS proposed rule (82 FR 35363 through 35364). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') from August 12 to September 12, 2016 expressed support for this data element, highlighting the importance of this information in supporting care coordination and care transitions. We also stated that some commenters had expressed concern about the appropriateness for standardization given: The prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how weaning status in particular relates to quality of care. These public comments guided our decision to propose a single data element focused on current use of invasive mechanical ventilation only, which does not attempt to capture weaning status. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Invasive Mechanical Ventilator data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Invasive Mechanical Ventilator data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Invasive Mechanical Ventilator data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Invasive Mechanical Ventilator data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Invasive Mechanical Ventilator data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing invasive mechanical ventilation, stakeholder input, and strong test results, we are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data for use in the HH QRP.

h. Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35364 through 35365), when we proposed a similar set of data elements related to IV medications, IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter. IV medications are administered via intravenous push, single, intermittent, or continuous infusion through a tube placed into the vein. Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness). The clinical indications for each of the sub-elements of the IV Medications data elements (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) are very different. IV antibiotics are used for severe infections when: The bioavailability of the oral form of the medication would be inadequate to kill the pathogen; an oral form of the medication does not exist; or the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''). IV anticoagulants are commonly used for hospitalized patients who have deep venous thrombosis, pulmonary embolism, or myocardial infarction, as well as those undergoing interventional cardiac procedures. Vasoactive medications refer to the IV administration of vasoactive drugs, including vasopressors, vasodilators, and continuous medication for pulmonary edema, which increase or decrease blood pressure or heart rate. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients and residents are receiving IV medication and the type

of medication provided by each PAC provider will improve quality of care.

The IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, and Other) data element we are proposing consists of a principal data element (IV Medications) and four response option sub-elements: Antibiotics, Anticoagulants, Vasoactive Medications, and Other. The Vasoactive Medications sub-element was not proposed in the CY 2018 HH PPS proposed rule (82 FR 35364 through 35365). We added the Vasoactive Medications sub-element to our proposal in order to harmonize the proposed IV Mediciations element with the data currently collected in the LCDS.

If the assessor indicates that the patient is receiving IV medications on the principal IV Medications data element, the assessor would then indicate which types of medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other). An IV Medications data element is currently in use on the MDS in SNFs and there is a related data element in OASIS that collects information on Intravenous and Infusion Therapies. For more information on the IV Medications data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

An IV Medications data element was first proposed as standardized patient assessment data elements in the CY 2018 HH PPS proposed rule (82 FR 35364 through 35365). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on Vasoactive Medications from August 12 to September 12, 2016 supported this data element with one commenter noting the importance of this data element in supporting care transitions. We also stated that those commenters had criticized the need for collecting specifically Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, public comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for IV Medications data elements.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the IV Medications data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Medications data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Medications data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the IV Medications data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing IV medications, stakeholder input, and strong test results, we are proposing that the IV Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other) data element with a principal data element and four sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data for use in the HH QRP.

i. Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35365), transfusion refers to introducing blood, blood products, or other fluid into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element consists of a single Transfusions data element. A data element on transfusion is currently in use in the MDS in SNFs (''Transfusions'') and a data element tested in the PAC PRD (''Blood Transfusions'') was found feasible for use in each of the four PAC settings. For more information on the Transfusions data element, we refer readers to the

document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

The Transfusions data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35365).

In response to our proposal in the CY 2018 HH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Transfusions data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Transfusions data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Transfusions data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Transfusions data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Transfusions data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing transfusions, stakeholder input, and strong test results, we are proposing that the Transfusions data element that is currently in use in the MDS meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Transfusions data element as standardized patient assessment data for use in the HH QRP.

j. Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal Dialysis) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35365 through 35366), dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The proposed data element, Dialysis (Hemodialysis, Peritoneal Dialysis) consists of the principal Dialysis data element and two response option sub-elements: Hemodialysis and Peritoneal Dialysis. If the assessor indicates that the patient is receiving dialysis on the principal Dialysis data element, the assessor would then indicate which type (Hemodialysis, Peritoneal Dialysis). The principal Dialysis data element is currently included on the MDS in SNFs and the LCDS for LTCHs and assesses the overall use of dialysis. As the result of public feedback described, in this proposed rule, we are proposing data elements that include the principal Dialysis data element and two sub-elements (Hemodialysis and Peritoneal Dialysis). For more information on the Dialysis data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

The Dialysis data element was first proposed as standardized patient assessment data elements in the CY 2018 HH PPS proposed rule (82 FR 35365 through 35366). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on a singular Hemodialysis data element from August 12 to September 12, 2016 supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. We also stated that those commenters had supported the singular Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. We also noted that several commenters had stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different

needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal Dialysis. We are proposing the expanded version of the Dialysis data element that includes two types of dialysis. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, we received public comments in support of the special services, treatments, and interventions data elements in general; no additional comments were received that were specific to the Dialysis data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Dialysis data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Dialysis data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Dialysis data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs'', available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although they did not specifically discuss the Dialysis data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing dialysis, stakeholder input, and strong test results, we are proposing that the Dialysis (Hemodialysis, Peritoneal Dialysis) data element with a principal data element and two sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Dialysis (Hemodialysis, Peritoneal Dialysis) data element as standardized patient assessment data for use in the HH QRP.

k. Intravenous (IV) Access (Peripheral IV, Midline, Central Line)

We are proposing that the IV Access (Peripheral IV, Midline, Central Line) data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35366), patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data element distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed data element, IV Access (Peripheral IV, Midline, Central Line), consists of the principal IV Access data element and three response option sub-elements: Peripheral IV, Midline, and Central Line. The proposed IV Access data element is not currently included on any of the PAC assessment instruments, although there is a related response option in the M1030 data element in the OASIS. We are proposing to replace the existing ''Intravenous or Infusion Therapy'' response option of the M1030 data element in the OASIS with the IV Access (Peripheral IV, Midline, Central Line) data element. For more information on the IV Access data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

The IV Access data element was first proposed as standardized patient assessment data elements in the CY 2018 HH PPS proposed rule (82 FR 35366). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input was submitted on one of the PAC PRD data elements, Central Line Management, from August 12 to September 12, 2016. A central line is one type of IV access. We stated that those commenters had supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters noted feasibility and importance of facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with expert input, described elsewhere in this proposed rule, we created an overarching IV Access data element with sub-elements for other types of IV access in addition to central lines (that is, peripheral IV and midline). This expanded version of IV Access is the data element being proposed. A summary report for the

August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the IV Access data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the IV Access data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the IV Access data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the IV Access data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the IV Access data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing IV access, stakeholder input, and strong test results, we are proposing that the IV access (Peripheral IV, Midline, Central Line) data element with a principal data element and three sub-elements meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the IV Access (Peripheral IV, Midline, Central Line) data element as standardized patient assessment data for use in the HH QRP.

l. Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35366 through 35367), parenteral nutrition/IV feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for parenteral nutrition/IV feeding indicates a clinical complexity that prevents the patient or resident from meeting his or her nutritional needs internally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries and maintenance of a central line. Therefore, assessing a patient's or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as embolism and sepsis.

The proposed data element consists of the single Parenteral/IV Feeding data element. The proposed Parenteral/IV Feeding data element is currently in use in the MDS for SNFs, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and OASIS. We are proposing to replace the existing ''Parenteral nutrition (TPN or lipids)'' response option of the M1030 data element in the OASIS with the proposed Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The Parenteral/IV Feeding data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35366 through 35367). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on Total Parenteral Nutrition (an item with nearly the same meaning as the proposed data element, but with the label used in the PAC PRD), which was included in a call for public input from August 12 to September 12, 2016. We stated that commenters had supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was renamed Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS in SNFs. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.* In response to our proposal in the CY 2018 HH PPS proposed rule, two commenters expressed support for the Parenteral/IV Feeding data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Parenteral/IV Feeding data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Parenteral/IV Feeding data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Parenteral/IV Feeding data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Parenteral/IV Feeding data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing parenteral/IV feeding, stakeholder input, and strong test results, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Parenteral/IV Feeding data element as standardized patient assessment data for use in the HH QRP.

m. Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35367 through 35368), the majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and, therefore, are important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[104] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The proposed data element consists of the single Feeding Tube data element. The Feeding Tube data element is currently included in the MDS for SNFs, and in the OASIS for HHAs, where it is labeled ''Enteral Nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)''. A related data element, collected in the IRF–PAI for IRFs (Tube/Parenteral Feeding), assesses use of both feeding tubes and parenteral nutrition. We are proposing to rename ''Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)'' data element to ''Feeding Tube,'' and adopt it as a SPADE for the HH QRP. For more information on the Feeding Tube data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The Feeding Tube data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35367 through 35368). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on an Enteral Nutrition data element (which is the same as the data element we are proposing in this proposed rule, but is used in the OASIS under a different name) from August 12 to September 12, 2016 supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was renamed Feeding Tube, indicating the presence of an assistive device. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, a few commenters expressed support for the Feeding Tube data element. A commenter also recommended that the term ''enteral feeding'' be used instead of ''feeding tube.''

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Feeding Tube data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Feeding Tube data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Feeding Tube data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Feeding Tube data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-*

[104] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: Can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

2014/IMPACT-Act-Downloads-and-Videos.html.

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing feeding tubes, stakeholder input, and strong test results, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Feeding Tube data element as standardized patient assessment data for use in the HH QRP.

n. Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35368), the Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[105]

In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients and residents on mechanically altered diets also require additional nursing supports such as individual feeding, or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element consists of the single Mechanically Altered Diet data element. The proposed data element for a mechanically altered diet is currently included on the MDS for SNFs. A related data element for modified food consistency/supervision is currently included on the IRF–PAI for IRFs. Another related data element is included in the OASIS for HHAs that collects information about independent eating that requires ''a liquid, pureed or ground meat diet.'' For more information on the Mechanically Altered Diet data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

The Mechanically Altered Diet data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35368).

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Mechanically Altered Diet data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Mechanically Altered Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Mechanically Altered Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Mechanically Altered Diet data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Mechanically Altered Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing mechanically altered diet, stakeholder input, and strong test results, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Mechanically Altered Diet data element as standardized patient assessment data for use in the HH QRP.

[105] Dempsey, D.T., Mullen, J.L., & Buzby, G.P. (1988). ''The link between nutritional status and clinical outcome: Can nutritional intervention modify it?'' *Am J of Clinical Nutrition,* 47(2): 352–356.

o. Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35368 through 35369), a therapeutic diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient's or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients and residents in PAC provides insight on the clinical complexity of these patients and residents and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The proposed data element consists of the single Therapeutic Diet data element. The Therapeutic Diet data element is currently in use in the MDS for SNFs. For more information on the Therapeutic Diet data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The Therapeutic Diet data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35368 through 35369).

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter expressed support for the Therapeutic Diet data element and encouraged CMS to align with the Academy of Nutrition and Dietetics definition of ''therapeutic diet.''

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Therapeutic Diet data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Therapeutic Diet data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Therapeutic Diet data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. Although the TEP did not specifically discuss the Therapeutic Diet data element, the TEP supported the assessment of the special services, treatments, and interventions included in the National Beta Test with respect to both admission and discharge. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing therapeutic diet, stakeholder input, and strong test results, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the Therapeutic data element as standardized patient assessment data for use in the HH QRP.

p. High-Risk Drug Classes: Use and Indication

We are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act.

Most patients and residents receiving PAC services depend on short- and long-term medications to manage their medical conditions. However, as a treatment, medications are not without risk; medications are in fact a leading cause of adverse events. A study by the U.S. Department of Health and Human Services found that 31 percent of adverse events that occurred in 2008 among hospitalized Medicare beneficiaries were related to medication.[106] Moreover, changes in a patient's condition, medications, and transitions between care settings put patients and residents at risk of medication errors and adverse drug events (ADEs). ADEs may be caused by medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.[107]

ADEs are known to occur across different types of healthcare. For example, the incidence of ADEs in the outpatient setting has been estimated at 1.15 ADEs per 100 person-months,[108] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[109] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[110] In addition, approximately half of all hospital-related medication errors and 20 percent of ADEs occur during transitions within, admission to, transfer to, or discharge

[106] U.S. Department of Health and Human Services. Office of Inspector General. Daniel R. Levinson. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI–06–09–00090. November 2010.

[107] Boockvar KS, Liu S, Goldstein N, Nebeker J, Siu A, Fried T. Prescribing discrepancies likely to cause adverse drug events after patient transfer. Qual Saf Health Care. 2009;18(1):32–6.

[108] Gandhi TK, Seger AC, Overhage JM, et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf* 2010;6:91–6. doi:10.1097/PTS.0b013e3181dcae06.

[109] Gurwitz JH, Field TS, Judge J, Rochon P, Harrold LR, Cadoret C, et al. The incidence of adverse drug events in two large academic long-term care facilities. *Am J Med.* 2005; 118(3):251±8. Epub 2005/03/05. *https://doi.org/10.1016/j.amjmed.2004.09.018.* PMID: 15745723.

[110] Hug BL, Witkowski DJ, Sox CM, Keohane CA, Seger DL, Yoon C, Matheny ME, Bates DW. Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. Kidney Int. 2009; 76:1192–1198. [PubMed: 19759525]

from a hospital.[111,112,113] ADEs are more common among older adults, who make up most patients and residents receiving PAC services. The rate of emergency department visits for ADEs is three times higher among adults 65 years of age and older compared to that among those younger than age 65.[114]

Understanding the types of medication a patient is taking and the reason for its use are key facets of a patient's treatment with respect to medication. Some classes of drugs are associated with more risk than others.[115] We are proposing one High-Risk Drug Class data element with six sub-elements. The six medication classes response options are: Anticoagulants; antiplatelets; hypoglycemics (including insulin); opioids; antipsychotics; and antibiotics. These drug classes are high-risk due to the adverse effects that may result from use. In particular, bleeding risk is associated with anticoagulants and antiplatelets;[116] [117] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics;[118] misuse is associated with opioids; [119] fractures and strokes are associated with antipsychotics;[120] [121] and various adverse events such as central nervous systems effects and gastrointestinal intolerance are associated with antimicrobials,[122] the larger category of medications that include antibiotics. Moreover, some medications in five of the six drug classes included as response options in this data element are included in the 2019 Updated Beers Criteria® list as potentially inappropriate medications for use in older adults.[123] Finally, although a complete medication list should record several important attributes of each medication (for example, dosage, route, stop date), recording an indication for the drug is of crucial importance.[124]

The High-Risk Drug Classes: Use and Indication data element requires an assessor to record whether or not a patient is taking any medications within six drug classes. The six response options for this data element are high-risk drug classes with particular relevance to PAC patients and residents, as identified by our data element contractor. The six data response options are Anticoagulants, Antiplatelets, Hypoglycemics, Opioids, Antipsychotics, and Antibiotics. For each drug class, the assessor is asked to indicate if the patient is taking any medications within the class, and, for drug classes in which medications were being taken, whether indications for all drugs in the class are noted in the medical record. For example, for the response option Anticoagulants, if the assessor indicates that the patient is taking anticoagulant medication, the assessor would then indicate if an indication is recorded in the medication record for the anticoagulant(s).

The High-Risk Drug Classes: Use and Indication data element that is being proposed as a SPADE was developed as part of a larger set of data elements to assess medication reconciliation, the process of obtaining a patient's multiple medication lists and reconciling any discrepancies. For more information on the High-Risk Drug Classes: Use and Indication data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

We sought public input on the relevance of conducting assessments on medication reconciliation and specifically on the proposed High-Risk Drug Classes: Use and Indication data element. Our data element contractor presented data elements related to medication reconciliation to the TEP convened on April 6 and 7, 2016. The TEP supported a focus on high-risk drugs, because of higher potential for harm to patients and residents, and were in favor of a data element to capture whether or not indications for medications were recorded in the medical record. A summary of the April 6 and 7, 2016 TEP meeting titled ''SPADE Technical Expert Panel Summary (First Convening)'' is available at: *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.* Medication reconciliation data elements were also discussed at a second TEP meeting on January 5 and 6, 2017, convened by our data element contractor.

At this meeting, the TEP agreed about the importance of evaluating the medication reconciliation process, but disagreed about how this could be accomplished through standardized assessment. The TEP also disagreed about the usability and appropriateness of using the Beers Criteria to identify high-risk medications,[125] although they were supportive of the other six drug classes named in the draft version of the data element, which are the six drug classes being proposed as response options in the proposed High-Risk Drug Classes: Use and Indications SPADE. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *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.*

We received public input on data elements related to medication reconciliation through a call for input published on the CMS Measures

[111] Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs.* 2005;28(2 Suppl):31–36.

[112] Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27–34.

[113] Gleason KM, Groszek JM, Sullivan C, Rooney D, Barnard C, Noskin GA. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health Syst Pharm.* 2004;61(16):1689–1695.

[114] Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US emergency department visits for outpatient adverse drug events, 2013–2014. *JAMA.* doi: 10.1001/jama.2016.16201.

[115] Ibid.

[116] Shoeb M, Fang MC. Assessing bleeding risk in patients taking anticoagulants. *J Thromb Thrombolysis.* 2013;35(3):312–319. doi: 10.1007/s11239–013–0899–7.

[117] Melkonian M, Jarzebowski W, Pautas E. Bleeding risk of antiplatelet drugs compared with oral anticoagulants in older patients with atrial fibrillation: a systematic review and meta-analysis. *J Thromb Haemost.* 2017;15:1500–1510. DOI: 10.1111/jth.13697.

[118] Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine,* New York. 2009; 76:234–243.

[119] Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32(4):725–735.

[120] Rigler SK, Shireman TI, Cook-Wiens GJ, Ellerbeck EF, Whittle JC, Mehr DR, Mahnken JD. Fracture risk in nursing home residents initiating antipsychotic medications. *J Am Geriatr Soc.* 2013; 61(5):715–722. [PubMed: 23590366]

[121] Wang S, Linkletter C, Dore D et al. Age, antipsychotics, and the risk of ischemic stroke in the Veterans Health Administration. *Stroke* 2012;43:28–31. doi:10.1161/STROKEAHA.111.617191.

[122] Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

[123] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2019; 00:1–21. DOI: 10.1111/jgs.15767.

[124] Li Y, Salmasian H, Harpaz R, Chase H, Friedman C. Determining the reasons for medication prescriptions in the EHR using knowledge and natural language processing. AMIA Annu Symp Proc. 2011;2011:768–76.

[125] American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 2015; 63:2227–2246.

Management System Blueprint website. In input received from April 26 to June 26, 2017, several commenters expressed support for the medication reconciliation data elements that were put on display, noting the importance of medication reconciliation in preventing medication errors and stating that the items seemed feasible and clinically useful. A few commenters were critical of the choice of ten drug classes posted during that comment period—the six drug classes in the proposed SPADE, along with antidepressants, diuretics, antianxiety, and hypnotics—arguing that ADEs are not limited to high-risk drugs, and raised issues related to training assessors to correctly complete a valid assessment of medication reconciliation. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May-June 2017 Public Comment Summary Report'' is available at: *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.*

The High-Risk Drug Classes: Use and Indication data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the High-Risk Drug Classes: Use and Indication data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the High-Risk Drug Classes: Use and Indication data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018. The TEP acknowledged the challenges of assessing medication safety, and were supportive of some of the data elements focused on medication reconciliation that were tested in the National Beta Test. The TEP was especially supportive of the focus on the six high-risk drug classes—which they identified from among other options during the second convening of the TEP, described previously—and of using these classes to assess whether the indication for a drug is recorded. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. These activities provided updates on the field-testing work and solicited feedback on data elements considered for standardization, including the High-Risk Drug Classes: Use and Indication data element. One stakeholder group was critical of the six drug classes included as response options in the High-Risk Drug Classes: Use and Indication data element, noting that potentially risky medications (for example, muscle relaxants) are not included in this list; that there may be important differences between drugs within classes (for example, more recent versus older style antidepressants); and that drug allergy information is not captured. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter questioned whether the time to complete the High-Risk Drug Classes: Use and Indication data element would differ across settings. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing high-risk drugs and for whether or not indications are noted for high-risk drugs, stakeholder input, and strong test results, we are proposing that the High-Risk Drug Classes: Use and Indication data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act and to adopt the High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data for use in the HH QRP.

3. Medical Condition and Comorbidity Data

Assessing medical conditions and comorbidities is critically important for care planning and safety for patients and residents receiving PAC services, and the standardized assessment of selected medical conditions and comorbidities across PAC providers is important for managing care transitions and understanding medical complexity.

We discuss our proposals for data elements related to the medical condition of pain as standardized patient assessment data. Appropriate pain management begins with a standardized assessment, and thereafter establishing and implementing an overall plan of care that is person-centered, multi-modal, and includes the treatment team and the patient. Assessing and documenting the effect of pain on sleep, participation in therapy, and other activities may provide information on undiagnosed conditions and comorbidities and the level of care required, and do so more objectively than subjective numerical scores. With that, we assess that taken separately and together, these proposed data elements are essential for care planning, consistency across transitions of care, and identifying medical complexities, including undiagnosed conditions. We also conclude that it is the standard of care to always consider the risks and benefits associated with a personalized care plan, including the risks of any pharmacological therapy, especially opioids.[126] We also conclude that in addition to assessing and appropriately treating pain through the optimum mix of pharmacologic, non-pharmacologic, and alternative therapies, while being cognizant of current prescribing guidelines, clinicians in partnership with patients are best able to mitigate factors that contribute to the current opioid crisis.[127] [128] [129]

[126] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[127] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[128] Fishman SM, Carr DB, Hogans B, et al. Scope and Nature of Pain- and Analgesia-Related Content

In alignment with our Meaningful Measures Initiative, accurate assessment of medical conditions and comorbidities of patients and residents in PAC is expected to make care safer by reducing harm caused in the delivery of care; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting effective communication and coordination of care. The proposed SPADEs will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing medical conditions and comorbidities are needed in order to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to medical conditions and comorbidities.

a. Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities)

In acknowledgement of the opioid crisis, we specifically are seeking comment on whether or not we should add these pain items in light of those concerns. Commenters should address to what extent collection of the data through patient queries might encourage providers to prescribe opioids.

We are proposing that a set of three data elements on the topic of Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act.

The practice of pain management began to undergo significant changes in the 1990s because the inadequate, non-standardized, non-evidence-based assessment and treatment of pain became a public health issue.[130] In pain management, a critical part of providing comprehensive care is performance of a thorough initial evaluation, including assessment of both the medical and any biopsychosocial factors causing or contributing to the pain, with a treatment plan to address the causes of pain and to manage pain that persists over time.[131] Quality pain management, based on current guidelines and evidence-based practices, can minimize unnecessary opioid prescribing both by offering alternatives or supplemental treatment to opioids and by clearly stating when they may be appropriate, and how to utilize risk-benefit analysis for opioid and non-opioid treatment modalities.[132]

Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step toward appropriate pain management in PAC settings. The National Pain Strategy called for refined assessment items on the topic of pain, and describes the need for these improved measures to be implemented in PAC assessments.[133] Further, the focus on pain *interference,* as opposed to pain intensity or pain frequency, was supported by the TEP convened by our data element contractor as an appropriate and actionable metric for assessing pain. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at *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.*

We appreciate the important concerns related to the misuse and overuse of opioids in the treatment of pain and to that end we note that in this proposed rule we have also proposed a SPADE that assess for the use of, as well as importantly the indication for that use of, high risk drugs, including opioids. Further, in the CY 2017 HH PPS final rule (81 FR 76780) we adopted the Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) HH QRP measure, which assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) including issues associated with use and misuse of opioids for pain management, when such issues were identified.

We also note that the proposed SPADEs related to pain assessment are not associated with any particular approach to management. Since the use of opioids is associated with serious complications, particularly in the elderly, an array of successful non-pharmacologic and non-opioid approaches to pain management may be considered.[134] [135] [136] PAC providers have historically used a range of pain management strategies, including non-steroidal anti-inflammatory drugs, ice, transcutaneous electrical nerve stimulation (TENS) therapy, supportive devices, acupuncture, and the like. In addition, non-pharmacological interventions implemented for pain management include, but are not limited to, biofeedback, application of heat/cold, massage, physical therapy, nerve block, stretching and strengthening exercises, chiropractic, electrical stimulation, radiotherapy, and ultrasound.[137] [138] [139]

We believe that standardized assessment of pain interference will support PAC clinicians in applying best-practices in pain management for chronic and acute pain, consistent with current clinical guidelines. For example,

of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass.* 2018;19(3):449–459. doi:10.1093/pm/pnx336.

[129] Fishman SM, Young HM, Lucas Arwood E, et al. Core competencies for pain management: results of an interprofessional consensus summit. Pain Med Malden Mass. 2013;14(7):971–981. doi:10.1111/pme.12107.

[130] Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington (DC): National Academies Press (US); 2011. *http://www.ncbi.nlm.nih.gov/books/NBK91497/.*

[131] Department of Health and Human Services: Pain Management Best Practices Inter-Agency Task Force. *Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.* Accessed April 1, 2019. *https://www.hhs.gov/sites/default/files/final-pmtf-draft-report-on-pain-management%20-best-practices-2018-12-12-html-ready-clean.pdf.*

[132] National Academies. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use.* Washington DC: National Academies of Sciences, Engineering, and Medicine; 2017.

[133] National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. *https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.*

[134] Chau, D.L., Walker, V., Pai, L., & Cho, L.M. (2008). Opiates and elderly: use and side effects. *Clinical interventions in aging, 3*(2), 273–8.

[135] Fine, P.G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management,* 38(2): S4–S14.

[136] Solomon, D.H., Rassen, J.A., Glynn, R.J., Garneau, K., Levin, R., Lee, J., & Schneeweiss, S. (2010). *Archives Internal Medicine,* 170(22):1979–1986.

[137] Byrd L. Managing chronic pain in older adults: a long-term care perspective. *Annals of Long-Term Care: Clinical Care and Aging.* 2013;21(12):34–40.

[138] Kligler, B., Bair, M.J., Banerjea, R. et al. (2018). Clinical Policy Recommendations from the VHA State-of-the-Art Conference on Non-Pharmacological Approaches to Chronic Musculoskeletal Pain. *Journal of General Internal Medicine, 33*(Suppl 1): 16. *https://doi.org/10.1007/s11606-018-4323-z.*

[139] Chou, R., Deyo, R., Friedly, J., et al. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of Internal Medicine, 166*(7):493–505.

the standardized assessment of both opioids and pain interference would support providers in successfully tapering patients/residents who arrive in the PAC setting with long-term use of opioids onto non-pharmacologic treatments and non-opioid medications, as recommended by the Society for Post-Acute and Long-Term Care Medicine,[140] and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis [141] which includes ''Better Pain Management.''

The Pain Interference data element set consists of three data elements: Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities. Pain Effect on Sleep assesses the frequency with which pain affects a patient's sleep. Pain Interference with Therapy Activities assesses the frequency with which pain interferes with a patient's ability to participate in therapies. The Pain Interference with Day-to-Day Activities assesses the extent to which pain interferes with a patient's ability to participate in day-to-day activities excluding therapy.

A similar data element on the effect of pain on activities is currently included in the OASIS. A similar data element on the effect on sleep is currently included in the MDS instrument in SNFs. We are proposing to add the Pain Interference data element set (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) to the OASIS and to remove M1242, Frequency of Pain Interfering with Patient's Activity or Movement. For more information on the Pain Interference data elements, we refer readers to the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

We sought public input on the relevance of conducting assessments on pain and specifically on the larger set of Pain Interview data elements included in the National Beta Test. The proposed data elements were supported by comments from the TEP meeting held by our data element contractor on April 7 to 8, 2016. The TEP affirmed the feasibility and clinical utility of pain as a concept in a standardized assessment. The TEP agreed that data elements on pain interference with ability to participate in therapies versus other activities should be addressed. Further, during a more recent convening of the same TEP on September 17, 2018, the TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements) because understanding the extent to which pain interferes with function would enable clinicians to determine the need for appropriate pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We held a public comment period in 2016 to solicit feedback on the standardization of pain and several other items that were under development in prior efforts, through a call for input published on the CMS Measures Management System Blueprint website. From the prior public comment period, we included several pain data elements (Pain Effect on Sleep; Pain Interference—Therapy Activities; Pain Interference—Other Activities) in a second call for public comment, also published on the CMS Measures Management System Blueprint website, open from April 26 to June 26, 2017. The items we sought comment on were modified from all stakeholder and test efforts. Commenters provided general comments about pain assessment in general in addition to feedback on the specific pain items. A few commenters shared their support for assessing pain, the potential for pain assessment to improve the quality of care, and for the validity and reliability of the data elements. Commenters affirmed that the item of pain and the effect on sleep would be suitable for PAC settings. Commenters' main concerns included redundancy with existing data elements, feasibility and utility for cross-setting use, and the applicability of interview-based items to patients and residents with cognitive or communication impairments, and deficits. A summary report for the April 26 to June 26, 2017 public comment period titled ''SPADE May-June 2017 Public Comment Summary Report'' is available at: *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.*

The Pain Interference data elements were included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Pain Interference data elements to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Pain Interference data elements in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on September 17, 2018 for the purpose of soliciting input on the proposed standardized patient assessment data elements. The TEP supported the interview-based pain data elements included in the National Beta Test. The TEP members were particularly supportive of the items that focused on how pain interferes with activities (that is, Pain Interference data elements), because understanding the extent to which pain interferes with function would enable clinicians to determine the need for pain treatment. A summary of the September 17, 2018 TEP meeting titled ''SPADE Technical Expert Panel Summary (Third Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, one commenter expressed strong support for the proposed pain SPADEs and was encouraged by the fact

[140] Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. *https://paltc.org/opioids%20in%20nursing%20homes.*

[141] *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

that this portion of the assessment surpasses pain presence. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Taking together the importance of assessing the effect of pain on function, stakeholder input, and strong test results, we are proposing that the set of Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) meet the definition of standardized patient assessment data with respect to medical conditions and comorbidities under section 1899B(b)(1)(B)(iv) of the Act and to adopt the Pain Interference data elements (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) as standardized patient assessment data for use in the HH QRP.

4. Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients and residents will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's or resident's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients and residents continue to have their vision and hearing needs met when they leave the facility. In addition, entities that receive Federal financial assistance, such as through Medicare Parts A, C, and D, must take appropriate steps to ensure effective communication for individuals with disabilities, including provision of appropriate auxiliary aids and services.[142]

In alignment with our Meaningful Measures Initiative, we expect accurate individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC to make care safer by reducing harm caused in the delivery of care; promoting effective prevention and treatment of chronic disease; strengthening person and family engagement as partners in their care; and promoting effective communication and coordination of care. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Therefore, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient's or resident's prognosis and reduce the possibility of adverse events.

Comments on the category of impairments were also submitted by stakeholders during the CY 2018 HH PPS proposed rule (82 FR 35369 through 35371) public comment period. We received public comments regarding the Hearing and Vision data elements; no additional comments were received about impairments in general.

We are inviting comment on our proposals to collect as standardized patient assessment data the following data with respect to impairments.

a. Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35369 through 35370), accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, and social functioning, and emotional health.[143] [144] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.[145] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[146] [147] [148] higher rates of incident cognitive impairment and cognitive decline,[149] and less time in occupational therapy.[150] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element consists of the single Hearing data element. This data consists of one question that assesses level of hearing impairment. This data element is currently in use in the MDS in SNFs. For more information on the Hearing data element, we refer readers to the document titled, ''Proposed Specifications for HH QRP

[142] Section 504 of the Rehabilitation Act of 1973, section1557 of the Affordable Care Act, and their respective implementing regulations. More information is available at: *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html,* and *https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html.*

[143] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[144] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012; 21(7):1135–1147.

[145] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991; 101(3):284–288.

[146] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options—a mini-review. *Gerontology.* 2010; 56(3):351–358.

[147] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011; 66A(5):582–590.

[148] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012; 21(7):1135–1147.

[149] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011; 68(2):214–220.

[150] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

Quality Measures and SPADEs'', available at: *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.*

The Hearing data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35369 through 35370). In that proposed rule, we stated that the proposal was informed by input we received through a call for input published on the CMS Measures Management System Blueprint website. Input submitted on the PAC PRD form of the data element (''Ability to Hear'') from August 12 to September 12, 2016, recommended that hearing, vision, and communication assessments be administered at the beginning of patient assessment process. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter noted that resources would be needed for a change in the OASIS to account for the Hearing data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Hearing data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Hearing data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Hearing data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs, available at: *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.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs, including the Hearing data element. The TEP affirmed the importance of standardized assessment of hearing impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Hearing data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Due to the relatively stable nature of hearing impairment, we are proposing that HHAs that submit the Hearing data element with respect to SOC will be deemed to have submitted with respect to discharge. Taking together the importance of assessing hearing, stakeholder input, and strong test results, we are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Hearing data element as standardized patient assessment data for use in the HH QRP.

b. Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act.

As described in the CY 2018 HH PPS proposed rule (82 FR 35370 through 35371), evaluation of an individual's ability to see is important for assessing risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and residents and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[151] [152] [153] [154] [155] [156] [157] Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the HH setting for care planning and defining resource use.

The proposed data element consists of the single Vision (Ability to See in Adequate Light) data element that consists of one question with five response categories. The Vision data element that we are proposing for standardization was tested as part of the development of the MDS for SNFs and is currently in use in that assessment. A similar data element, but with different wording and fewer response option categories, is in use in the OASIS. We are proposing to add the Vision (Ability to See in Adequate Light) data element to the OASIS to replace M1200, Vision. For more information on the Vision data element, we refer readers to the document titled, ''Proposed

[151] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[152] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[153] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[154] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[155] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[156] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[157] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

The Vision data element was first proposed as a standardized patient assessment data element in the CY 2018 HH PPS proposed rule (82 FR 35370 through 35371). In that proposed rule, we stated that the proposal was informed by input we received from August 12 to September 12, 2016, on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories) through a call for input published on the CMS Measures Management System Blueprint website. The data element on which we solicited input differed from the proposed data element, but input submitted from August 12 to September 12, 2016 supported the assessment of vision in PAC settings and the useful information a vision data element would provide. We also stated that commenters had noted that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element over the form put forward in public comment, citing the widespread use of this data element. A summary report for the August 12 to September 12, 2016 public comment period titled ''SPADE August 2016 Public Comment Summary Report'' is available at *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.*

In response to our proposal in the CY 2018 HH PPS proposed rule, one commenter noted that resources would be needed for a change in the OASIS to account for the Vision data element.

Subsequent to receiving comments on the CY 2018 HH PPS proposed rule, the Vision data element was included in the National Beta Test of candidate data elements conducted by our data element contractor from November 2017 to August 2018. Results of this test found the Vision data element to be feasible and reliable for use with PAC patients and residents. More information about the performance of the Vision data element in the National Beta Test can be found in the document titled, ''Proposed Specifications for HH QRP Quality Measures and SPADEs,'' available at: *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.*

In addition, our data element contractor convened a TEP on January 5 and 6, 2017 for the purpose of soliciting input on all the SPADEs including the Vision data element. The TEP affirmed the importance of standardized assessment of vision impairment in PAC patients and residents. A summary of the January 5 and 6, 2017 TEP meeting titled ''SPADE Technical Expert Panel Summary (Second Convening)'' is available at: *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.*

We also held Special Open Door Forums and small-group discussions with PAC providers and other stakeholders in 2018 for the purpose of updating the public about our ongoing SPADE development efforts. Finally, on November 27, 2018, our data element contractor hosted a public meeting of stakeholders to present the results of the National Beta Test and solicit additional comments. General input on the testing and item development process and concerns about burden were received from stakeholders during this meeting and via email through February 1, 2019. Additionally, a commenter expressed support for the Vision data element and suggested administration at the beginning of the patient assessment to maximize utility. A summary of the public input received from the November 27, 2018 stakeholder meeting titled ''Input on SPADEs Received After November 27, 2018 Stakeholder Meeting'' is available at: *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.*

Due to the relatively stable nature of vision impairment, we are proposing that HHAs that submit the Vision data element with respect to SOC will be deemed to have submitted with respect to discharge. Taking together the importance of assessing vision, stakeholder input, and strong test results, we are proposing that the Vision data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act and to adopt the Vision data element as standardized patient assessment data for use in the HH QRP.

5. Proposed New Category: Social Determinants of Health

a. Proposed Social Determinants of Health Data Collection To Inform Measures and Other Purposes

Subparagraph (A) of section 2(d)(2) of the IMPACT Act requires CMS to assess appropriate adjustments to quality measures, resource measures, and other measures, and to assess and implement appropriate adjustments to payment under Medicare based on those measures, after taking into account studies conducted by ASPE on social risk factors (described elsewhere in this proposed rule) and other information, and based on an individual's health status and other factors. Subparagraph (C) of section 2(d)(2) of the IMPACT Act further requires the Secretary to carry out periodic analyses, at least every three years, based on the factors referred to subparagraph (A) so as to monitor changes in possible relationships. Subparagraph (B) of section 2(d)(2) of the IMPACT Act requires CMS to collect or otherwise obtain access to data necessary to carry out the requirement of the paragraph (both assessing adjustments described previously in such subparagraph (A) and for periodic analyses in such subparagraph (C)). Accordingly we are proposing to use our authority under subparagraph (B) of section 2(d)(2) of the IMPACT Act to establish a new data source for information to meet the requirements of subparagraphs (A) and (C) of section 2(d)(2). In this rule, we are proposing to collect and access data about social determinants of health (SDOH) in order to perform CMS' responsibilities under subparagraphs (A) and (C) of section 2(d)(2) of the IMPACT Act, as explained in more detail elsewhere in this proposed rule. Social determinants of health, also known as social risk factors, or health-related social needs, are the socioeconomic, cultural and environmental circumstances in which individuals live that impact their health. We are proposing to collect information on seven proposed SDOH SPADE data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and

social isolation; a detailed discussion of each of the proposed SDOH data elements is found in section IV.A.7.f.(ii). of this proposed rule.

We are also proposing to use the OASIS, the current version being OASIS–D, described as the PAC assessment instrument for home health agencies under section 1899B(a)(2)(B)(i) of the Act, to collect these data via an existing data collection mechanism. We believe this approach will provide CMS with access to data with respect to the requirements of section 2(d)(2) of the IMPACT Act, while minimizing the reporting burden on PAC health care providers by relying on a data reporting mechanism already used and an existing system to which PAC providers are already accustomed.

The IMPACT Act includes several requirements applicable to the Secretary, in addition to those imposing new data reporting obligations on certain PAC providers as discussed in section IV.A.7.f.(2). of this proposed rule. Subparagraphs (A) and (B) of section 2(d)(1) of the IMPACT Act require the Secretary, acting through the Office of the Assistant Secretary for Planning and Evaluation (ASPE), to conduct two studies that examine the effect of risk factors, including individuals' socioeconomic status, on quality, resource use and other measures under the Medicare program. The first ASPE study was completed in December 2016 and is discussed in this proposed rule, and the second study is to be completed in the fall of 2019. We recognize that ASPE, in its studies, is considering a broader range of social risk factors than the SDOH data elements in this proposal, and address both PAC and non-PAC settings. We acknowledge that other data elements may be useful to understand, and that some of those elements may be of particular interest in non-PAC settings. For example, for beneficiaries receiving care in the community, as opposed to an in-patient facility, housing stability and food insecurity may be more relevant. We will continue to take into account the findings from both of ASPE's reports in future policy making.

One of the ASPE's first actions under the IMPACT Act was to commission the National Academies of Sciences, Engineering and Medicine (NASEM) to define and conceptualize socioeconomic status for the purposes of ASPE's two studies under section 2(d)(1) of the IMPACT Act. The NASEM convened a panel of experts in the field and conducted an extensive literature review. Based on the information collected, the 2016 NASEM panel report titled, ''Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors,'' concluded that the best way to assess how social processes and social relationships influence key health-related outcomes in Medicare beneficiaries is through a framework of social risk factors instead of socioeconomic status. Social risk factors discussed in the NASEM report include socioeconomic position, race, ethnicity, gender, social context, and community context. These factors are discussed at length in chapter 2 of the NASEM report, entitled ''Social Risk Factors.'' [158] Consequently NASEM framed the results of its report in terms of ''social risk factors'' rather than ''socioeconomic status'' or ''sociodemographic status.'' The full text of the ''Social Risk Factors'' NASEM report is available for reading on the website at *https://www.nap.edu/read/21858/chapter/1.*

Each of the data elements we are proposing to collect and access pursuant to our authority under section 2(d)(2)(B) of the IMPACT Act is identified in the 2016 NASEM report as a social risk factor that has been shown to impact care use, cost and outcomes for Medicare beneficiaries. CMS uses the term social determinants of health (SDOH) to denote social risk factors, which is consistent with the objectives of Healthy People 2020.[159]

ASPE issued its first Report to Congress, entitled ''Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs,'' under section 2(d)(1)(A) of the IMPACT Act on December 21, 2016.[160] Using NASEM's social risk factors framework, ASPE focused on the following social risk factors, in addition to disability: (1) Dual enrollment in Medicare and Medicaid as a marker for low income; (2) residence in a low-income area; (3) Black race; (4) Hispanic ethnicity; and (5) residence in a rural area. ASPE acknowledged that the social risk factors examined in its report were limited due to data availability. The report also noted that the data necessary to meaningfully attempt to reduce disparities and identify and reward improved outcomes for beneficiaries with social risk factors have not been collected consistently on a national level in post-acute care settings. Where these data have been collected, the collection frequently involves lengthy questionnaires. More information on the Report to Congress on Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs, including the full report, is available on the website at *https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs-reports.*

Section 2(d)(2) of the IMPACT Act relates to CMS activities and imposes several responsibilities on the Secretary relating to quality, resource use, and other measures under Medicare. As mentioned previously, under of subparagraph (A) of section 2(d)(2) of the IMPACT Act, the Secretary is required, on an ongoing basis, taking into account the ASPE studies and other information, and based on an individual's health status and other factors, to assess appropriate adjustments to quality, resource use, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. Section 2(d)(2)(A)(i) of the IMPACT Act applies to measures adopted under subsections (c) and (d) of section 1899B of the Act and to other measures under Medicare. However, our ability to perform these analyses, and assess and make appropriate adjustments is hindered by limits of existing data collections on SDOH data elements for Medicare beneficiaries. In its first study in 2016, in discussing the second study, ASPE noted that information related to many of the specific factors listed in the IMPACT Act, such as health literacy, limited English proficiency, and Medicare beneficiary activation, are not available in Medicare data.

Subparagraph 2(d)(2)(A) of the IMPACT Act specifically requires the Secretary to take the studies and considerations from ASPE's reports to Congress, as well as other information as appropriate, into account in assessing and implementing adjustments to measures and related payments based on measures in Medicare. The results of the ASPE's first study demonstrated that Medicare beneficiaries with social risk factors tended to have worse outcomes on many quality measures, and providers who treated a disproportionate share of beneficiaries with social risk factors tended to have worse performance on quality measures. As a result of these findings, ASPE

[158] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Chapter 2. Washington, DC: The National Academies Press.

[159] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[160] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Payment Programs. Washington, DC.

suggested a three-pronged strategy to guide the development of value-based payment programs under which all Medicare beneficiaries receive the highest quality healthcare services possible. The three components of this strategy are to: (1) Measure and report quality of care for beneficiaries with social risk factors; (2) set high, fair quality standards for care provided to all beneficiaries; and (3) reward and support better outcomes for beneficiaries with social risk factors. In discussing how measuring and reporting quality for beneficiaries with social risk factors can be applied to Medicare quality payment programs, the report offered nine considerations across the three-pronged strategy, including enhancing data collection and developing statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

Congress, in section 2(d)(2)(B) of the IMPACT Act, required the Secretary to collect or otherwise obtain access to the data necessary to carry out the provisions of paragraph (2) of section 2(d)(2) of the IMPACT Act through both new and existing data sources. Taking into consideration NASEM's conceptual framework for social risk factors discussed previously, ASPE's study, and considerations under section 2(d)(1)(A) of the IMPACT Act, as well as the current data constraints of ASPE's first study and its suggested considerations, we are proposing to collect and access data about SDOH under section 2(d)(2) of the IMPACT Act. Our collection and use of the SDOH data described in section IV.A.7.f.(i). of this proposed rule, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal (in section IV.A.7.f.(2). of this proposed rule) and our authority to require submission of that data for use as SPADE under section 1899B(a)(1)(B) of the Act.

Accessing standardized data relating to the SDOH data elements on a national level is necessary to permit CMS to conduct periodic analyses, to assess appropriate adjustments to quality measures, resource use measures, and other measures, and to assess and implement appropriate adjustments to Medicare payments based on those measures. We agree with ASPE's observations, in the value-based purchasing context, that the ability to measure and track quality, outcomes, and costs for beneficiaries with social risk factors over time is critical as policymakers and providers seek to reduce disparities and improve care for these groups. Collecting the data as proposed will provide the basis for our periodic analyses of the relationship between an individual's health status and other factors and quality, resource, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. These data would also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reduce costs and improve the quality of care for all beneficiaries. Collecting and accessing SDOH data in this way also supports the three-part strategy put forth in the first ASPE report, specifically ASPE's consideration to enhance data collection and develop statistical techniques to allow measurement and reporting of performance for beneficiaries with social risk factors on key quality and resource use measures.

For the reasons discussed previously, we are proposing under section 2(d)(2) of the IMPACT Act, to collect the data on the following SDOH: (1) Race, as described in section V.G.5.b.(1). of this proposed rule; (2) Ethnicity, described in section V.G.5.b.(1). of this proposed rule; (3) Preferred Language, as described in section V.G.5.(ii).(2). of this proposed rule; (4) Interpreter Services, as described in section V.G.5.b.(2). of this proposed rule; (5) Health Literacy, as described in section V.G.5.b.(3). of this proposed rule; (6) Transportation, as described in section V.G.5.(ii).(4). of this proposed rule; and (7) Social Isolation, as described in section V.G.5.b.(5). of this proposed rule. These data elements are discussed in more detail in section V.G.5. of this proposed rule.

b. Standardized Patient Assessment Data

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect SPADEs with respect to other categories deemed necessary and appropriate. We are proposing to create a Social Determinants of Health SPADE category under section 1899B(b)(1)(B)(vi) of the Act. In addition to collecting SDOH data for the purposes outlined previously, under section 2(d)(2)(B), we are also proposing to collect as SPADE these same data elements (race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation) under section 1899B(b)(1)(B)(vi) of the Act. We believe that this proposed new category of Social Determinants of Health will inform provider understanding of individual patient risk factors and treatment preferences, facilitate coordinated care and care planning, and improve patient outcomes. We are proposing to deem this category necessary and appropriate, for the purposes of SPADE, because using common standards and definitions for PAC data elements is important in ensuring interoperable exchange of longitudinal information between PAC providers and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process from post-acute care settings.

All of the Social Determinants of Health data elements we are proposing under section 1899B(b)(1)(B)(vi) of the Act have the capacity to take into account treatment preferences and care goals of patients and to inform our understanding of patient complexity and risk factors that may affect care outcomes. While acknowledging the existence and importance of additional SDOH, we are proposing to assess some of the factors relevant for patients receiving post-acute care that PAC settings are in a position to impact through the provision of services and supports, such as connecting patients with identified needs with transportation programs, certified interpreters, or social support programs.

As previously mentioned, and described in more detail elsewhere in this proposed rule, we are proposing to adopt the following seven data elements as SPADE under the proposed Social Determinants of Health category: Race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. To select these data elements, we reviewed the research literature, a number of validated assessment tools and frameworks for addressing SDOH currently in use (for example, Health Leads, NASEM, Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD–10), and we engaged in discussions with stakeholders. We also prioritized balancing the reporting burden for PAC providers with our policy objective to collect SPADEs that will inform care planning and coordination and quality improvement across care settings. Furthermore, incorporating SDOH data elements into care planning has the potential to reduce readmissions and help beneficiaries achieve and maintain their health goals.

We also considered feedback received during a listening session that we held on December 13, 2018. The purpose of the listening session was to solicit feedback from health systems, research organizations, advocacy organizations, state agencies, and other members of the public on collecting patient-level data on SDOH across care settings, including consideration of race, ethnicity, spoken

language, health literacy, social isolation, transportation, sex, gender identity, and sexual orientation. We also gave participants an option to submit written comments. A full summary of the listening session, titled ''Listening Session on Social Determinants of Health Data Elements: Summary of Findings,'' includes a list of participating stakeholders and their affiliations, and is available at *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.*

(1) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.[161] [162] [163] [164] [165] Despite the trend toward overall improvements in quality of care and health outcomes, the Agency for Healthcare Research and Quality, in its National Healthcare Quality and Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[166] For example, racial and ethnic minorities tend to have higher rates of infant mortality, diabetes and other chronic conditions, and visits to the emergency department, and lower rates of having a usual source of care and receiving immunizations such as the flu vaccine.[167] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[168] However, our ability to identify and address racial and ethnic health disparities has historically been constrained by data limitations, particularly for smaller populations groups such as Asians, American Indians and Alaska Natives, and Native Hawaiians and other Pacific Islanders.[169]

The ability to improve understanding of and address racial and ethnic disparities in PAC outcomes requires the availability of better data. There is currently a Race and Ethnicity data element, collected in the MDS, LCDS, IRF–PAI, and OASIS, that consists of a single question, which aligns with the 1997 Office of Management and Budget (OMB) minimum data standards for federal data collection efforts.[170] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. The 1997 OMB Standard also lists two minimum categories of ethnicity: (1) Hispanic or Latino; and (2) Not Hispanic or Latino. The 2011 HHS Data Standards requires a two-question format when self-identification is used to collect data on race and ethnicity. Large federal surveys such as the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and the National Survey on Drug Use and Health, have implemented the 2011 HHS race and ethnicity data standards. CMS has similarly updated the Medicare Current Beneficiary Survey, Medicare Health Outcomes Survey, and the Health Insurance Marketplace Application for Health Coverage with the 2011 HHS data standards. More information about the HHS Race and Ethnicity Data Standards are available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

We are proposing to revise the current Race and Ethnicity data element for purposes of this proposal to conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity. Rather than one data element that assesses both race and ethnicity, we are proposing two separate data elements: One for Race and one for Ethnicity, that would conform with the 2011 HHS Data Standards and the 1997 OMB Standard. In accordance with the 2011 HHS Data Standards, a two-question format would be used for the proposed race and ethnicity data elements.

The proposed Race data element asks, ''What is your race?'' We are proposing to include 14 response options under the race data element: (1) White; (2) Black or African American; (3) American Indian or Alaska Native; (4) Asian Indian; (5) Chinese; (6) Filipino; (7) Japanese; (8) Korean; (9) Vietnamese; (10) Other Asian; (11) Native Hawaiian; (12) Guamanian or Chamorro; (13) Samoan; and, (14) Other Pacific Islander.

The proposed Ethnicity data element asks, ''Are you Hispanic, Latino/a, or Spanish origin?'' We are proposing to include five response options under the ethnicity data element: (1) Not of Hispanic, Latino/a, or Spanish origin; (2) Mexican, Mexican American, Chicano; (3) Puerto Rican; (4) Cuban; and (5) Another Hispanic, Latino, or Spanish Origin.

We believe that the two proposed data elements for race and ethnicity conform to the 2011 HHS Data Standards for person-level data collection, while also meeting the 1997 OMB minimum data standards for race and ethnicity, because under those standards, more detailed information on population groups can be collected if those additional categories can be aggregated into the OMB minimum standard set of categories.

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the importance of improving response options for race and ethnicity as a component of health care assessments and for monitoring disparities. Some stakeholders emphasized the importance of allowing for self-identification of race and ethnicity for more categories than are included in the 2011 HHS Standard to better reflect state and local diversity, while acknowledging the burden of coding an open-ended health care assessment question across different settings.

We believe that the proposed modified race and ethnicity data elements more accurately reflect the diversity of the U.S. population than the

[161] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

[162] Fiscella, K. and Sanders, M.R. Racial and Ethnic Disparities in the Quality of Health Care. (2016). Annual Review of Public Health. 37:375–394.

[163] 2018 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Reports. Baltimore, MD: U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services; February 28, 2018.

[164] Smedley, B.D., Stith, A.Y., & Nelson, A.R. (2003). Unequal treatment: confronting racial and ethnic disparities in health care. Washington, DC, National Academy Press.

[165] Chase, J., Huang, L. and Russell, D. (2017). Racial/ethnic disparities in disability outcomes among post-acute home care patients. J of Aging and Health. 30(9):1406–1426.

[166] National Healthcare Quality and Disparities Reports. (December 2018). Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/research/findings/nhqrdr/index.html.*

[167] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

[168] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). *http://minorityhealth.hhs.gov/omh/browse.*aspx?lvl=4&lvlid=19.

[169] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A, Negussie Y, Geller A, et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/.*

[170] ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Notice of Decision)''. **Federal Register** 62:210 (October 30, 1997) pp. 58782–58790. Available from: *https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf.*

current race/ethnicity data element included in MDS, LCDS, IRF–PAI, and OASIS.[171] [172] [173] [174] We believe, and research consistently shows, that improving how race and ethnicity data are collected is an important first step in improving quality of care and health outcomes. Addressing disparities in access to care, quality of care, and health outcomes for Medicare beneficiaries begins with identifying and analyzing how SDOH, such as race and ethnicity, align with disparities in these areas.[175] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[176] By collecting and analyzing these data, CMS and other healthcare entities will be able to identify challenges and monitor progress. The growing diversity of the U.S. population and knowledge of racial and ethnic disparities within and across population groups supports the collection of more granular data beyond the 1997 OMB minimum standard for reporting categories. The 2011 HHS race and ethnicity data standard includes additional detail that may be used by PAC providers to target quality improvement efforts for racial and ethnic groups experiencing disparate outcomes. For more information on the Race and Ethnicity data elements, we refer readers to the document titled ''Proposed Specifications for HH QRP Measures and Standardized Patient Assessment Data Elements,'' available at *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*.

In an effort to standardize the submission of race and ethnicity data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Race and Ethnicity data elements described previously as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we are proposing to replace the current Race/Ethnicity data element, M0140, with the proposed Race and Ethnicity data elements. Due to the stable nature of Race/Ethnicity, we are proposing that HHAs that submit the Race and Ethnicity SPADEs with respect to SOC only will be deemed to have submitted those SPADEs with respect to SOC, ROC, and discharge, because it is unlikely that the assessment of those SPADEs with respect to SOC will differ from the assessment of the same SPADES with respect to ROC and discharge.

(2) Preferred Language and Interpreter Services

More than 64 million Americans speak a language other than English at home, and nearly 40 million of those individuals have limited English proficiency (LEP).[177] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[178] [179] [180] Communication with individuals with LEP is an important component of high quality health care, which starts by understanding the population in need of language services. Unaddressed language barriers between a patient and provider care team negatively affects the ability to identify and address individual medical and non-medical care needs, to convey and understand clinical information, as well as discharge and follow up instructions, all of which are necessary for providing high quality care. Understanding the communication assistance needs of patients with LEP, including individuals who are Deaf or hard of hearing, is critical for ensuring good outcomes.

Presently, the preferred language of patients and need for interpreter services are assessed in two PAC assessment tools. The LCDS and the MDS use the same two data elements to assess preferred language and whether a patient or resident needs or wants an interpreter to communicate with health care staff. The MDS initially implemented preferred language and interpreter services data elements to assess the needs of SNF residents and patients and inform care planning. For alignment purposes, the LCDS later adopted the same data elements for LTCHs. The 2009 NASEM (formerly Institute of Medicine) report on standardizing data for health care quality improvement emphasizes that language and communication needs should be assessed as a standard part of health care delivery and quality improvement strategies.[181]

In developing our proposal for a standardized language data element across PAC settings, we considered the current preferred language and interpreter services data elements that are in LCDS and MDS. We also considered the 2011 HHS Primary Language Data Standard and peer-reviewed research. The current preferred language data element in LCDS and MDS asks, ''What is your preferred language?'' Because the preferred language data element is open-ended, the patient is able to identify their preferred language, including American Sign Language (ASL). Finally, we considered the recommendations from the 2009 NASEM (formerly Institute of Medicine) report, ''Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement.'' In it, the committee recommended that organizations evaluating a patient's language and communication needs for health care purposes, should collect data on the preferred spoken language and on an individual's assessment of his/her level of English proficiency.

A second language data element in LCDS and MDS asks, ''Do you want or need an interpreter to communicate with a doctor or health care staff?'' and

[171] Penman-Aguilar, A., Talih, M., Huang, D., Moonesinghe, R., Bouye, K., Beckles, G. (2016). Measurement of Health Disparities, Health Inequities, and Social Determinants of Health to Support the Advancement of Health Equity. J Public Health Manag Pract. 22 Suppl 1: S33–42.

[172] Ramos, R., Davis, J.L., Ross, T., Grant, C.G., Green, B.L. (2012). Measuring health disparities and health inequities: Do you have REGAL data? Qual Manag Health Care. 21(3):176–87.

[173] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[174] ''Revision of Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity: Proposals From Federal Interagency Working Group (Notice and Request for Comments).'' **Federal Register** 82: 39 (March 1, 2017) p. 12242.

[175] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Community-Based Solutions to Promote Health Equity in the United States; Baciu A. Negussie Y. Geller A. et al., editors. Communities in Action: Pathways to Health Equity. Washington (DC): National Academies Press (US); 2017 Jan 11. 2, The State of Health Disparities in the United States. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK425844/*.

[176] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[177] U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

[178] Karliner LS, Kim SE, Meltzer DO, Auerbach AD. Influence of language barriers on outcomes of hospital care for general medicine inpatients. J Hosp Med. 2010 May–Jun;5(5):276–82. doi: 10.1002/jhm.658.

[179] Kim EJ, Kim T, Paasche-Orlow MK, et al. Disparities in Hypertension Associated with Limited English Proficiency. J Gen Intern Med. 2017 Jun;32(6):632–639. doi: 10.1007/s11606–017–3999–9.

[180] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[181] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

includes yes or no response options. In contrast, the 2011 HHS Primary Language Data Standard recommends either a single question to assess how well someone speaks English or, if more granular information is needed, a two-part question to assess whether a language other than English is spoken at home and if so, identify that language. However, neither option allows for a direct assessment of a patient's preferred spoken or written language nor whether they want or need interpreter services for communication with a doctor or care team, both of which are an important part of assessing patient needs and the care planning process. More information about the HHS Data Standard for Primary Language is available on the website at *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=54.*

Research consistently recommends collecting information about an individual's preferred spoken language and evaluating those responses for purposes of determining language access needs in health care.[182] However, using ''preferred spoken language'' as the metric does not adequately account for people whose preferred language is ASL, which would necessitate adopting an additional data element to identify visual language. The need to improve the assessment of language preferences and communication needs across PAC settings should be balanced with the burden associated with data collection on the provider and patient. Therefore we are proposing to use the Preferred Language and Interpreter Services data elements currently in use on the MDS and LCDS, on the OASIS.

In addition, we received feedback during the December 13, 2018 listening session on the importance of evaluating and acting on language preferences early to facilitate communication and allowing for patient self-identification of preferred language. Although the discussion about language was focused on preferred spoken language, there was general consensus among participants that stated language preferences may or may not accurately indicate the need for interpreter services, which supports collecting and evaluating data to determine language preference, as well as the need for interpreter services. An alternate suggestion was made to inquire about preferred language specifically for discussing health or health care needs. While this suggestion does allow for ASL as a response option, we do not have data indicating how useful this question might be for assessing the desired information and thus we are not including this question in our proposal.

Improving how preferred language and need for interpreter services data are collected is an important component of improving quality by helping PAC providers and other providers understand patient needs and develop plans to address them. For more information on the Preferred Language and Interpreter Services data elements, we refer readers to the document titled ''Proposed Specifications for HH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *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.*

In an effort to standardize the submission of language data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Preferred Language and Interpreter Services data elements currently used on the LCDS and MDS, and described previously, as SPADES with respect to the Social Determinants of Health category.

(3) Health Literacy

The Department of Health and Human Services defines health literacy as ''the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.'' [183] Similar to language barriers, low health literacy can interfere with communication between the provider and patient and the ability for patients or their caregivers to understand and follow treatment plans, including medication management. Poor health literacy is linked to lower levels of knowledge about health, worse health outcomes, and the receipt of fewer preventive services, but higher medical costs and rates of emergency department use.[184]

Health literacy is prioritized by Healthy People 2020 as an SDOH.[185] Healthy People 2020 is a long-term, evidence-based effort led by the Department of Health and Human Services that aims to identify nationwide health improvement priorities and improve the health of all Americans. Although not designated as a social risk factor in NASEM's 2016 report on accounting for social risk factors in Medicare payment, the NASEM report noted that Health literacy is impacted by other social risk factors and can affect access to care as well as quality of care and health outcomes.[186] Assessing for health literacy across PAC settings would facilitate better care coordination and discharge planning. A significant challenge in assessing the health literacy of individuals is avoiding excessive burden on patients and health care providers. The majority of existing, validated health literacy assessment tools use multiple screening items, generally with no fewer than four, which would make them burdensome if adopted in MDS, LCDS, IRF–PAI, and OASIS.

The Single Item Literacy Screener (SILS) question asks, ''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'' Possible response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always. The SILS question, which assesses reading ability (a primary component of health literacy), tested reasonably well against the 36 item Short Test of Functional Health Literacy in Adults (S–TOFHLA), a thoroughly vetted and widely adopted health literacy test, in assessing the likelihood of low health literacy in an adult sample from primary care practices participating in the Vermont Diabetes Information System.[187] [188] The S–TOFHLA is a more

[182] Guerino, P. and James, C. Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period. Centers for Medicare & Medicaid Services, Office of Minority Health. Data Highlight: Volume 7—April 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf.*

[183] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National action plan to improve health literacy. Washington (DC): Author; 2010.

[184] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for social risk factors in Medicare payment: Identifying social risk factors. Washington, DC: The National Academies Press.

[185] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[186] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.* Washington, DC: 2016.

[187] Morris, N.S., MacLean, C.D., Chew, L.D., & Littenberg, B. (2006). The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC family practice, 7, 21. doi:10.1186/1471–2296–7–21.

[188] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A.

complex assessment instrument developed using actual hospital related materials such as prescription bottle labels and appointment slips, and often considered the instrument of choice for a detailed evaluation of health literacy.[189] Furthermore, the S–TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[190] Given that SILS is publicly available, shorter and easier to administer than the full health literacy screen, and research found that a positive result on the SILS demonstrates an increased likelihood that an individual has low health literacy, we are proposing to use the single-item reading question for health literacy in the standardized data collection across PAC settings. We believe that use of this data element will provide sufficient information about the health literacy of HH patients to facilitate appropriate care planning, care coordination, and interoperable data exchange across PAC settings.

In addition, we received feedback during the December 13, 2018 SDOH listening session on the importance of recognizing health literacy as more than understanding written materials and filling out forms, as it is also important to evaluate whether patients understand their conditions. However, the NASEM recently recommended that health care providers implement health literacy universal precautions instead of taking steps to ensure care is provided at an appropriate literacy level based on individualized assessment of health literacy.[191] Given the dearth of Medicare data on health literacy and gaps in addressing health literacy in practice, we recommend the addition of a health literacy data element.

The proposed Health Literacy data element is consistent with considerations raised by NASEM and other stakeholders and research on health literacy, which demonstrates an impact on health care use, cost, and outcomes.[192] For more information on the proposed Health Literacy data element, we refer readers to the document titled ''Proposed Specifications for HH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *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.*

In an effort to standardize the submission of health literacy data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the SILS question, described previously for the Health Literacy data element, as SPADE under the Social Determinants of Health category. We are proposing to add the Health Literacy data element to the OASIS.

(4) Transportation

Transportation barriers commonly affect access to necessary health care, causing missed appointments, delayed care, and unfilled prescriptions, all of which can have a negative impact on health outcomes.[193] Access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management. Adopting a data element to collect and analyze information regarding transportation needs across PAC settings would facilitate the connection to programs that can address identified needs. We are therefore proposing to adopt as SPADE a single transportation data element that is from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) assessment tool and currently part of the Accountable Health Communities (AHC) Screening Tool.

The proposed Transportation data element from the PRAPARE tool asks, ''Has a lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The three response options are: (1) Yes, it has kept me from medical appointments or from getting my medications; (2) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; and (3) No. The patient would be given the option to select all responses that apply. We are proposing to use the transportation data element from the PRAPARE Tool, with permission from National Association of Community Health Centers (NACHC), after considering research on the importance of addressing transportation needs as a critical SDOH.[194]

The proposed data element is responsive to research on the importance of addressing transportation needs as a critical SDOH and would adopt the Transportation item from the PRAPARE tool.[195] This data element comes from the national PRAPARE social determinants of health assessment protocol, developed and owned by NACHC, in partnership with the Association of Asian Pacific Community Health Organization, the Oregon Primary Care Association, and the Institute for Alternative Futures. Similarly the Transportation data element used in the AHC Screening Tool was adapted from the PRAPARE tool. The AHC screening tool was implemented by the Center for Medicare and Medicaid Innovation's AHC Model and developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including transportation. While the transportation access data element in the AHC screening tool serves the same purposes as our proposed SPADE collection about transportation barriers, the AHC tool has binary yes or no response options that do not differentiate between challenges for medical versus non-medical appointments and activities. We believe that this is an important nuance for informing PAC discharge planning to a community setting, as transportation needs for non-medical activities may differ than for medical activities and should be taken into account.[196] We believe that use of this data element will provide sufficient information about transportation barriers to medical and non-medical care for HH patients to facilitate appropriate discharge planning and care coordination across PAC

(2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[189] University of Miami, School of Nursing & Health Studies, Center of Excellence for Health Disparities Research. Test of Functional Health Literacy in Adults (TOFHLA). (March 2019). Available from: *https://elcentro.sonhs.miami.edu/research/measures-library/tofhla/index.html.*

[190] Nurss, J.R., Parker, R.M., Williams, M.V., &Baker, D.W. David W. (2001). TOFHLA. Peppercorn Books & Press. Available from: *http://www.peppercornbooks.com/catalog/information.php?info_id=5.*

[191] Hudson, S., Rikard, R.V., Staiculescu, I. & Edison, K. (2017). Improving health and the bottom line: The case for health literacy. In Building the case for health literacy: Proceedings of a workshop. Washington, DC: The National Academies Press.

[192] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press.

[193] Syed, S.T., Gerber, B.S., and Sharp, L.K. (2013). Traveling Towards Disease: Transportation Barriers to Health Care Access. J Community Health. 38(5): 976–993.

[194] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.www.aha.org/transportation.*

[195] Health Research & Educational Trust. (2017, November). Social determinants of health series: Transportation and the role of hospitals. Chicago, IL. Available at *www.aha.org/transportation.*

[196] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

settings. As such, we are proposing to adopt the Transportation data element from PRAPARE. More information about development of the PRAPARE tool is available on the website at *https://protect2.fireeye.com/url?k=7cb6eb44-20e2f238-7cb6da7b-0cc47adc5fa2-1751cb986c8c2f8c&u=http://www.nachc.org/prapare.*

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the impact of transportation barriers on unmet care needs. While recognizing that there is no consensus in the field about whether providers should have responsibility for resolving patient transportation needs, discussion focused on the importance of assessing transportation barriers to facilitate connections with available community resources.

Adding a Transportation data element to the collection of SPADE would be an important step to identifying and addressing SDOH that impact health outcomes and patient experience for Medicare beneficiaries. For more information on the Transportation data element, we refer readers to the document titled ''Proposed Specifications for HH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *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.*

In an effort to standardize the submission of transportation data among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Transportation data element described previously as SPADE with respect to the proposed Social Determinants of Health category. If finalized as proposed, we would add the Transportation data element to the OASIS.

(5) Social Isolation

Distinct from loneliness, social isolation refers to an actual or perceived lack of contact with other people, such as living alone or residing in a remote area.[197] [198] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[199] [200] [201] Post-acute care providers are well-suited to design and implement programs to increase social engagement of patients, while also taking into account individual needs and preferences. Adopting a data element to collect and analyze information about social isolation for patients receiving HH services and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts.

We are proposing to adopt as SPADE a single social isolation data element that is currently part of the AHC Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress, and asks, ''How often do you feel lonely or isolated from those around you?'' The five response options are: (1) Never; (2) Rarely; (3) Sometimes; (4) Often; and (5) Always.[202] The AHC Screening Tool was developed by a panel of interdisciplinary experts that looked at evidence-based ways to measure SDOH, including social isolation. More information about the AHC Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

In addition, we received stakeholder feedback during the December 13, 2018 SDOH listening session on the value of receiving information on social isolation for purposes of care planning. Some stakeholders also recommended assessing social isolation as an SDOH as opposed to social support.

The proposed Social Isolation data element is consistent with NASEM considerations about social isolation as a function of social relationships that impacts health outcomes and increases mortality risk, as well as the current work of a NASEM committee examining how social isolation and loneliness impact health outcomes in adults 50 years and older. We believe that adding a Social Isolation data element would be an important component of better understanding patient complexity and the care goals of patients, thereby facilitating care coordination and continuity in care planning across PAC settings. For more information on the Social Isolation data element, we refer readers to the document titled ''Proposed Specifications for HH QRP Measures and Standardized Patient Assessment Data Elements,'' available on the website at *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.*

In an effort to standardize the submission of data about social isolation among IRFs, HHAs, SNFs and LTCHs, for the purposes outlined in section 1899B(a)(1)(B) of the Act, while minimizing the reporting burden, we are proposing to adopt the Social Isolation data element described previously as SPADE with respect to the proposed Social Determinants of Health category. We are proposing to add the Social Isolation data element to the OASIS.

J. Proposed Codification of the Home Health Quality Reporting Program Requirements

To promote alignment of the HH QRP and the SNF QRP, IRF QRP, and LTCH QRP regulatory text, we believe that with the exception of the provision governing the 2 percentage point reduction to the update of the unadjusted national standardized prospective payment rate, it is appropriate to codify the requirements that apply to the HH QRP in a single section of our regulations. Accordingly, we are proposing to amend 42 CFR chapter IV, subchapter G by creating a new § 484.245, titled ''Home Health Quality Reporting Program''.

The provisions we are proposing to codify are as follows:

- The HH QRP participation requirements at § 484.245(a) (72 FR 49863).
- The HH QRP data submission requirements at § 484.245(b)(1), including—

++ Data on measures specified under section 1899B(c)(1) and 1899B(d)(1) of the Act;

++ Standardized patient assessment data required under section 1899B(b)(1) of the Act (82 FR 51735 through 51736); and

++ Quality data specified under section 1895(b)(3)(B)(v)(II) of the Act including the HHCAHPS survey data submission requirements at § 484.245(b)(1)(iii)(A) through (E)

[197] Tomaka, J., Thompson, S., and Palacios, R. (2006). The Relation of Social Isolation, Loneliness, and Social Support to Disease Outcomes Among the Elderly. J of Aging and Health. 18(3): 359–384.

[198] Social Connectedness and Engagement Technology for Long-Term and Post-Acute Care: A Primer and Provider Selection Guide. (2019). Leading Age. Available at *https://www.leadingage.org/white-papers/social-connectedness-and-engagement-technology-long-term-and-post-acute-care-primer-and#1.1.*

[199] Landeiro, F., Barrows, P., Nuttall Musson, E., Gray, A.M., and Leal, J. (2017). Reducing Social Loneliness in Older People: A Systematic Review Protocol. BMJ Open. 7(5): e013778.

[200] Ong, A.D., Uchino, B.N., and Wethington, E. (2016). Loneliness and Health in Older Adults: A Mini-Review and Synthesis. Gerontology. 62:443–449.

[201] Leigh-Hunt, N., Bagguley, D., Bash, K., Turner, V., Turnbull, S., Valtorta, N., and Caan, W. (2017). An overview of systematic reviews on the public health consequences of social isolation and loneliness. Public Health. 152:157–171.

[202] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

(redesignated from § 484.250(b) through (c)(3) and striking § 484.250(a)(2)).

- The HH QRP data submission form, manner, and timing requirements at § 484.245(b)(2).
- The HH QRP exceptions and extension requirements at § 484.245(c) (redesignated from § 484.250(d)(1) through (d)(4)(ii)).
- The HH QRP's reconsideration policy at § 484.245(d) (redesignated from § 484.250(e)(1) through (4)).
- The HH QRP appeals policy at § 484.245(e) (redesignated from § 484.250(f)).

We also note the following codification proposals:

- The addition of the HHCAHPS and HH QRP acronyms to the definitions at § 484.205.
- The removal of the regulatory provision in § 484.225(b) regarding the unadjusted national prospective 60-day episode rate for HHAs that submit their quality data as specified by the Secretary.
- The redesignation of the regulatory provision in § 484.225(c) to § 484.225(b) regarding the unadjusted national prospective 60-day episode rate for HHAs that do not submit their quality data as specified by the Secretary.
- The redesignation of the regulatory provision in § 484.225(d) to § 484.225(c) regarding the national, standardized prospective 30-day payment amount. The cross-reference in newly redesignated paragraph (c) would also be revised.

K. Home Health Care Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey (HHCAHPS)

We are proposing to remove Question 10 from all HHCAHPS Surveys (both mail surveys and telephone surveys) which says, ''In the last 2 months of care, did you and a home health provider from this agency talk about pain?'' which is one of seven questions (they are questions 3, 4, 5, 10, 12, 13 and 14) in the ''Special Care Issues'' composite measure, beginning July 1, 2020. The ''Special Care Issues'' composite measure also focuses on home health agency staff discussing home safety, the purpose of the medications that are being taken, side effects of medications, and when to take medications. In the initial development of the HHCAHPS Survey, this question was included in the survey since home health agency staff talk about pain to identify any emerging issues (for example, wounds that are getting worse) every time they see their home health patients.

We are proposing to remove pain questions from the HHCAHPS Survey and pain items from the OASIS data sets to avoid potential unintended consequences that may arise from their inclusion in CMS surveys and datasets. The reason that CMS is proposing removing this particular pain question is consistent with the proposed removal of pain items from OASIS in section IV.D.1. of this proposed rule and also consistent with the removal of pain items from the Hospital CAHPS Survey. The removal of pain questions from CMS surveys and removal of pain items from CMS data sets is to avoid potential unintended consequences that arise from their inclusion in CMS surveys and datasets. We welcome comments about the proposed removal of Q10 from the HHCAHPS Survey. In the initial development of the HHCAHPS Survey, this question was included in the survey, and, consequently, from the ''Special Care Issues'' measure. The HHCAHPS Survey is available on the official website for HHCAHPS, at *https://homehealthcahps.org.*

I. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Background

Section 484.250(a), requires HHAs to submit OASIS data and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Not all OASIS data described in § 484.55(b) and (d) are necessary for purposes of complying with the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. OASIS data items may be used for other purposes unrelated to the HH QRP, including payment, survey and certification, 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 determining HH QRP compliance.

2. Proposed Schedule for Reporting the Transfer of Health Information Quality Measures Beginning With the CY 2022 HH QRP

As discussed in section V.E. of this proposed rule, we are proposing to adopt the Transfer of Health Information to Provider–Post-Acute Care (PAC) and Transfer of Health Information to Patient–Post-Acute Care (PAC) quality measures beginning with the CY 2022 HH QRP. We are also proposing that HHAs would report the data on those measures using the OASIS. We are proposing that HHAs would be required to collect data on both measures for patients beginning with patients discharged or transferred on or after January 1, 2021. HHAs would be required to report these data for the CY 2022 HH QRP at discharge and transfer between January 1, 2021 and June 30, 2021. Following the initial reporting period for the CY 2022 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2021 through June 30, 2022 for the CY 2023 HH QRP.

3. Proposed Schedule for Reporting Standardized Patient Assessment Data Elements Beginning With the CY 2022 HH QRP

As discussed in section V.G. of this proposed rule, we are proposing to adopt additional SPADEs beginning with the CY 2022 HH QRP. We are proposing that HHAs would report the data using the OASIS. HHAs would be required to collect the SPADEs for episodes beginning or ending on or after January 1, 2021. We are also proposing that HHAs that submit the Hearing, Vision, Race, and Ethnicity SPADEs with respect to SOC will be deemed to have submitted those SPADEs with respect to SOC, ROC, and discharge, because it is unlikely that the assessment of those SPADEs with respect to SOC will differ from the assessment of the same SPADES with respect to ROC or discharge. HHAs would be required to report the remaining SPADES for the CY 2022 HH QRP at SOC, ROC, and discharge time points between January 1, 2021 and June 30, 2021. Following the initial reporting period for the CY 2022 HH QRP, subsequent years for the HH QRP would be based on 12 months of such data reporting beginning with July 1, 2021 through June 30, 2022 for the CY 2023 HH QRP.

4. Input Sought To Expand the Reporting of OASIS Data Used for the HH QRP To Include Data on All Patients Regardless of Their Payer

We continue to believe that the reporting of all-payer data under the HH QRP would add value to the program and provide a more accurate representation of the quality provided by HHA's. In the CY 2018 HH PPS final rule (82 FR 51736 through 51737), we received and responded to comments sought for data reporting related to assessment based measures, specifically on whether we should require quality data reporting on all HH patients, regardless of payer, where feasible. Several commenters supported data collection of all patients regardless of payer but other commenters did express concerns about the burden imposed on the HHAs as a result of OASIS reporting

for all patients, including healthcare professionals spending more time with documentation and less time providing patient care, and the need to increase staff hours or hire additional staff. A commenter requested CMS provide additional explanation of what the benefit would be to collecting OASIS data on all patients regardless of payer.

We are sensitive to the issue of burden associated with data collection and acknowledge concerns about the additional burden required to collect quality data on all patients. We are aware that while some providers use a separate assessment for private payers, many HHA's currently collect OASIS data on all patients regardless of payer to assist with clinical and work flow implications associated with maintaining two distinct assessments. We believe collecting OASIS data on all patients regardless of payer will allow us to ensure data that is representative of quality provided to all patients in the HHA setting and therefore, allow us to better determine whether HH Medicare beneficiaries receive the same quality of care that other patients receive. We also believe it is the overall goal of the IMPACT Act to standardize data and measures in the four PAC programs to permit longitudinal analysis of the data. The absence of all payer data limits CMS's ability to compare all patients receiving services in each PAC setting, as was intended by the Act.

We plan to propose to expand the reporting of OASIS data used for the HH QRP to include data on all patients, regardless of their payer, in future rulemaking. Collecting data on all HHA patients, regardless of their payer would align our data collection requirements under the HH QRP with the data collection requirements currently adopted for the Long-Term Care Hospital (LTCH) QRP and the Hospice QRP. Additionally, collection of data on all patients, regardless of their payer is currently being proposed in the FY 2020 rules for the Skilled Nursing Facility (SNF) QRP (84 FR 17678 through 17679) and the Inpatient Rehabilitation Facilities (IRF) QRP (84 FR 17326 through 17327). To assist us regarding a future proposal, we are seeking input on the following questions related to requiring quality data reporting on all HH patients, regardless of payer:

- Do you agree there is a need to collect OASIS data for the HH QRP on all patients regardless of payer?
- What percentage of your HHA's patients are you not currently reporting OASIS data for the HH QRP?
- Are there burden issues that need to be considered specific to the reporting of OASIS data on all HH patients, regardless of their payer?
- What differences, if any, do you notice in patient mix or in outcomes between those patients that you currently report OASIS data, and those patients that you do not report data for the HH QRP?
- Are there other factors that should be considered prior to proposing to expand the reporting of OASIS data used for the HH QRP to include data on all patients, regardless of their payer?

As stated previously, there is no proposal in this rule to expand the reporting of OASIS data used for the HH QRP to include data on all HHA patients regardless of payer. However we look forward to receiving comments on this topic, including the questions noted previously, and will take all recommendations received into consideration.

VI. Medicare Coverage of Home Infusion Therapy Services

A. Background and Overview

1. Background

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 began on January 1, 2019 and will 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.

In the CY 2019 HH PPS final rule (83 FR 32340), we finalized the implementation of temporary transitional payments for home infusion therapy services to begin on January 1, 2019. In addition, we implemented the establishment of regulatory authority for the oversight of national accrediting organizations (AOs) that accredit home infusion therapy suppliers, and their CMS-approved home infusion therapy accreditation programs.

2. Overview of Infusion Therapy

Infusion drugs can be administered 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 and no coinsurance for the first 60 days. 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 (77 FR

68210).[203] Medicare also makes a separate payment to the physician or hospital outpatient departments (HOPD) for administering the drug. 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 service, 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 generally excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.[204] The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.[205]

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. Generally, the components needed to perform home infusion include the drug (for example, antivirals, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are usually 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. These 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 training and education, 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 the services required to furnish the drug, (that is, preparation and dispensing), 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. In accordance with section 50401 of the Bipartisan Budget Act (BBA) of 2018, beginning on January 1, 2019, for CYs 2019 and 2020, Medicare implemented temporary transitional payments for home infusion therapy services furnished in coordination with the furnishing of transitional home infusion drugs. This payment, for home infusion therapy services, is only made if a beneficiary is furnished certain drugs and biologicals administered through an item of covered DME, and payable only to suppliers enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies (including the drug). With regard to the coverage of the home infusion drugs, 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 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. Additionally, in order for the infusion pump to be covered under the DME benefit, it must be appropriate for use in the home (§ 414.202).

Only certain types of infusion pumps are covered under the DME benefit. The Medicare *National Coverage Determinations Manual,* chapter 1, part 4, section 280.14 describes the types of infusion pumps that are covered under the DME benefit.[206] For DME external infusion pumps, Medicare Part B covers the infusion drugs and other supplies and services necessary for the effective use of the pump. Through the Local Coverage Determination (LCD) for External Infusion Pumps (L33794), 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.

3. Home Infusion Therapy Legislation

a. 21st Century Cures Act

Effective January 1, 2021, section 5012 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) created a separate Medicare Part B benefit category under section 1861(s)(2)(GG) of the Act for coverage of home infusion therapy services needed for the safe and effective administration of certain drugs and biologicals 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 infusion pump and supplies (including home infusion drugs) will continue to be covered under the Part B 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 paid for as DME), remote monitoring, and other monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier, which are furnished in the individual'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

[203] *https://www.govinfo.gov/content/pkg/FR-2012-11-15/pdf/2012-26902.pdf.*

[204] Medicare Benefit Policy Manual, chapter 15, ''Covered Medical and Other Health Services'', section 50.2—Determining Self-Administration of Drug or Biological found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[205] *www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.*

[206] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.html.*

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 an 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 qualified 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)(2) of the Act specifies certain items that ''the Secretary may consider'' in developing the HIT payment system: ''the costs of furnishing infusion therapy in the home, consult[ation] with home infusion therapy suppliers, . . . payment amounts for similar items and services under this part and part A, and . . . payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy)''. 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 Consumer Price Index for all urban consumers (CPI–U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Under section 1834(u)(1)(A)(iii), the single payment amount 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. This statutory provision limits the single payment amount so that it 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. Bipartisan Budget Act of 2018

Section 50401 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1834(u) of the Act by adding a new paragraph (7) that established 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 payment covers the same items and services as defined in section 1861(iii)(2)(A) and (B) of the Act, furnished in coordination with the furnishing of transitional home infusion drugs. 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 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 DME as defined under section 1861(n) of the Act. The definition of ''home infusion drug'' excludes ''a self-administered drug or biological on a self-administered drug exclusion list'' but the definition of ''transitional home infusion drug'' notes that this exclusion shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of 1834(u)(7)(C) of the Act. Section 1834(u)(7)(C) of the Act sets out the Healthcare Common Procedure Coding System (HCPCS) codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794), as the drugs covered during the temporary transitional period. In addition, section 1834(u)(7)(C) of the Act states that the Secretary shall assign to an appropriate payment category drugs which are covered under the DME LCD for External Infusion Pumps and billed under HCPCS codes J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified), or billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in sub-regulatory guidance as a home infusion drug.

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)(A) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. Section 1842(u)(7)(F) of the Act defines ''eligible home infusion supplier'' as a supplier who is enrolled in Medicare as 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.

As set out at section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories, as

identified by their corresponding HCPCS codes, for which a single amount will be paid for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 includes subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals. The payment category for subsequent transitional home infusion drug additions to the LCD and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the DME MACs.

In accordance with section 1834(u)(7)(D) of the Act, each payment category is paid at amounts in accordance with the Physician Fee Schedule (PFS) for each infusion drug administration calendar day in the individual's home for drugs assigned to such category, without geographic adjustment. Section 1834(u)(7)(E)(ii) of the Act requires that 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 will be made.

4. Summary of CY 2019 Home Infusion Therapy Provisions

In the CY 2019 Home Health Prospective Payment System (HH PPS) final rule (83 FR 56579) we finalized the implementation of the home infusion therapy services temporary transitional payments under paragraph (7) of section 1834(u) of the Act. These services are furnished in the individual's home to an individual who is 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 where there is a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. Only eligible home infusion suppliers can bill for the temporary transitional payments. Therefore, in accordance with section 1834(u)(7)(F) of the Act, we clarified that this means that existing DME suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies, who comply with Medicare's DME Supplier and Quality Standards, and maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered, are considered eligible home infusion suppliers.

Section 1834(u)(7)(C) of the Act assigns transitional home infusion drugs, identified by the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794),[207] into three payment categories, for which we established a single payment amount in accordance with section 1834(u)(7)(D) of the Act. This section states that each single payment amount per category will be paid at amounts equal to the amounts determined under the PFS established under section 1848 of the Act for services furnished during the year for codes and units of such codes, without geographic adjustment. Therefore, we created a new HCPCS G-code for each of the three payment categories and finalized the billing procedure for the temporary transitional payment for eligible home infusion suppliers. We stated that the eligible home infusion supplier would submit, in line-item detail on the claim, a G-code for each infusion drug administration calendar day. The claim should include the length of time, in 15-minute increments, for which professional services were furnished. The G-codes can be billed separately from, or on the same claim as, the DME, supplies, or infusion drug, and are processed through the DME MACs. On August 10, 2018, we issued Change Request: R4112CP: Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020 [208] outlining the requirements for the claims processing changes needed to implement this payment.

And finally, we finalized the definition of ''infusion drug administration calendar day'' in regulation as 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 (42 CFR 486.505). Section 1834(u)(7)(E)(i) of the Act clarifies that this definition is with respect to the furnishing of ''transitional home infusion drugs'' and ''home infusion drugs'' to an individual by an ''eligible home infusion supplier'' and a ''qualified home infusion therapy supplier.'' The definition of ''infusion drug administration calendar day'' applies to both the temporary transitional payment in CYs 2019 and 2020 and the permanent home infusion therapy benefit to be implemented beginning in CY 2021. Although we finalized this definition in regulation in the CY 2019 HH PPS final rule with comment (83 FR 56583), we stated that we would carefully monitor the effects of this definition on access to care and we stated that, if warranted and if within the limits of our statutory authority, we would engage in additional rulemaking our guidance regarding this definition. In that same rule, we also solicited additional comments on this interpretation and on its effects on access to care. We have been monitoring utilization of home infusion therapy services beginning on January 1, 2019; however, we do not have sufficient data on utilization yet to determine the effects on access to care. We will be addressing those comments received in response to the CY 2019 HH PPS final rule with comment as well as those received for this proposed rule in the CY 2020 HH PPS final rule.

B. CY 2020 Temporary Transitional Payment Rates for Home Infusion Therapy Services

As previously noted, section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished to administer home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of the same items and services including professional services, training and education, monitoring, and remote monitoring 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 began on January 1, 2019 and will 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. The list of transitional home infusion drugs and the payment categories for the temporary transitional payment for home infusion therapy services can be

[207] *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=83&Date=05%2f15%2f2019&DocID=L33794&bc=iAAAABAAAAAA&.*

[208] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf.*

found in Tables 55 and 56 in the CY 2019 HH PPS proposed rule (83 FR 32465 and 32466).[209]

Section 1834(u)(7)(D)(i) of the Act sets the payment amounts for each category equal to the amounts determined under the PFS established under section 1848 of the Act for services furnished during the year for codes and units for such codes specified without application of geographic wage adjustment under section 1848(e) of the Act. That is, the payment amounts are based on the PFS rates for the Current Procedural Terminology (CPT) codes corresponding to each payment category. For eligible home infusion suppliers to bill the temporary transitional payments for home infusion therapy services for an infusion drug administration calendar day, we created a G-code associated with each of the three payment categories. The J-codes for eligible home infusion drugs, the G-codes associated with each of the three payment categories, and instructions for billing for the temporary transitional home infusion therapy payment are found in Change Request 10836, ''Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020.'' [210]

Therefore, in this proposed rule, we are updating the temporary transitional payments based on the CPT code payment amounts in the CY 2020 PFS. At the time of publication of this proposed rule, we do not yet have the CY 2020 PFS rates. However, actual payments starting on January 1, 2020 will be based on the PFS amounts as specified in section 1834(u)(7)(D) of the Act as discussed earlier. We will publish these updated rates in the CY 2020 physician fee schedule final rule.[211]

C. Proposed Home Infusion Therapy Services for CY 2021 and Subsequent Years

As previously described in this proposed rule, upon completion of the temporary transitional payments for home infusion therapy services at the end of CY 2020, payment for home infusion therapy services under Section 5012 of the 21st Century Cures Act (Pub. L. 114–255) would be implemented beginning January 1, 2021. However, we are making proposals regarding home infusion therapy services for CY 2021 and beyond in the CY 2020 HH PPS proposed rule to allow adequate time for eligible home infusion therapy suppliers to make any necessary software and business process changes for implementation on January 1, 2021.

1. Scope of Benefit and Conditions for Payment

Section 1861(iii) of the Act establishes certain provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers. These provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services, outlining beneficiary qualifications and plan of care requirements, and establishing who can bill for payment under the benefit.

a. Home Infusion Drugs

In the 2019 Home Health Prospective Payment System (HH PPS) proposed rule (83 FR 32466) we discussed the relationship between the home infusion therapy benefit and the DME benefit. We stated that, as there is no separate Medicare Part B DME payment for the professional services associated with the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps, we consider the home infusion therapy benefit to be a separate payment in addition to the existing payment for the DME equipment, accessories, and supplies (including the home infusion drug) made under the DME benefit. Consistent with the definition of ''home infusion therapy,'' the home infusion therapy payment explicitly and separately pays for the professional services related to the administration of the drugs identified on the DME LCD for external infusion pumps, which are furnished in the individual's home. For purposes of the temporary transitional payments for home infusion therapy services in CYs 2019 and 2020, the term ''transitional home infusion drug'' includes the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794). However, while section 1834(u)(7)(A)(iii) of the Act defines the term ''transitional home infusion drug,'' section 1834(u)(7)(A)(iii) of the Act does not specify the HCPCS codes for home infusion drugs for which home infusion therapy services would be covered beginning in CY 2021. We received comments on the CY 2019 HH PPS proposed rule requesting clarification of the drugs and biologicals identified as ''home infusion drugs'' and whether, under the permanent benefit to be implemented in 2021, the scope of drugs would expand beyond the drugs identified for coverage under the temporary transitional payment. Consequently, we stated in the CY 2019 HH PPS final rule (83 FR 56584) that we would continue to examine the criteria for ''home infusion drugs'' for coverage of home infusion therapy services beginning in 2021.

Section 1861(iii)(3)(C) of the Act defines ''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 (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. This definition not only specifies that the drug or biological must be administered through a pump that is an item of DME, but references the statutory definition of DME at 1861(n) of the Act. This means that ''home infusion drugs'' are drugs and biologicals administered through a pump that is covered under the Medicare Part B DME benefit. Therefore, we interpret this statutory reference in section 1861(iii)(3)(C) of the Act to mean that Medicare payment for home infusion therapy is for services furnished in coordination with the furnishing of the infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps.[212]

In order to be covered under the Part B DME benefit, the external infusion pump must be classified as an item of DME, the related drug must be reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, an infusion pump is necessary to safely administer the drug, and it has to meet all other applicable Medicare statutory and regulatory requirements.[213] The DME LCD for External Infusion Pumps (L33794) specifies the ''reasonable and necessary'' coverage criteria in order to support coverage of external infusion pumps for the indications identified on the National Coverage Determination (NCD) for Infusion Pumps.[214] The DME

[209] *https://www.govinfo.gov/content/pkg/FR-2018-07-12/pdf/2018-14443.pdf*

[210] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf.*

[211] *https://www.cms.gov/apps/physician-fee-schedule/.*

[212] *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD.*

[213] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD.*

[214] *https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=*

Medicare Administrative Contractors (MACs) make the determinations for which drugs meet this coverage criteria, and in general, update the LCDs quarterly or as needed. There are four MACs, covering various jurisdictions, that work together to issue the same LCD under their contracts. Therefore, we believe that the term ''home infusion drugs'' for coverage of home infusion therapy services, refers to the drugs and biologicals identified on the DME LCD for External Infusion Pumps (L33794). Therefore, we are proposing to carry forward the definition of ''home infusion drugs'' as defined for the temporary, transitional payment for home infusion therapy services (83 FR 56579). That is, for home infusion therapy services furnished on and after January 1, 2021, we are proposing that ''home infusion drugs'' are parenteral drugs and biologicals 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 covered under the Medicare Part B DME benefit.

For external infusion pumps, the supplier must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction in accordance with 42 CFR 424.57(c)(12). The teaching and training for the safe and effective use of the external infusion pump is covered and paid for under the DME benefit. By contrast, the services covered under the home infusion therapy benefit are intended to provide teaching and training on the provision of home infusion drugs besides the teaching and training covered under the DME benefit, as we described in the CY2019 HH PPS proposed rule (83 FR 32467). The teaching and training provided under the home infusion therapy benefit is not intended to duplicate teaching and training that is already covered under the DME benefit. We are soliciting comments on carrying forward the definition of ''home infusion drugs'' as described previously to the permanent home infusion therapy services benefit beginning on January 1, 2021.

b. Patient Eligibility and Plan of Care Requirements

Subparagraphs (A) and (B) of section 1861(iii)(1) of the Act set forth beneficiary eligibility and plan of care requirements for ''home infusion therapy.'' In accordance with section 1861(iii)(1)(A) of the Act, the beneficiary 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 assistant. In accordance with section 1861(iii)(1)(B) of the Act, the beneficiary must also be under a plan of care, established by a physician (defined at section 1861(r)(1) of the Act), prescribing the type, amount, and duration of infusion therapy services that are to be furnished, and periodically reviewed, in coordination with the furnishing of home infusion drugs under Part B based on these statutory requirements. Section 486.520 sets out the standards of care that qualified home infusion therapy suppliers must meet in order to participate in Medicare. Section 486.520(a) requires that all patients be under the care of an applicable provider, as defined at § 486.505. Section 486.520(b) requires that the qualified home infusion therapy supplier must ensure that all patients have a plan of care established by a physician that prescribes the type, amount, and duration of home infusion therapy services that are to be furnished. The plan of care must 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 individualized care and services necessary to meet the patient-specific needs. Section 486.520(c) requires that the qualified home infusion therapy supplier must ensure that the patient plan of care is periodically reviewed by a physician.

We are proposing to make a number of revisions to the regulations to implement the home infusion therapy services payment system beginning with January 1, 2021, as outlined in section VI.D of this proposed rule. We propose to add a new 42 CFR part 414, subpart P, to implement the home infusion therapy services conditions for payment. In accordance with the standards at § 486.520, we are proposing conforming regulations text, at § 414.1505, requiring that home infusion therapy services be furnished to an eligible beneficiary by, or under arrangement with, a qualified home infusion therapy supplier that meets the health and safety standards for qualified home infusion therapy suppliers at § 486.520(a) through (c). We also propose at § 414.1510 that, as a condition for payment, qualified home infusion therapy suppliers ensure that a beneficiary meets certain eligibility criteria for coverage of services, as well as ensure that certain plan of care requirements are met. We propose at § 414.1510 to require that a beneficiary 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 assistant. Additionally, we propose at § 414.1510, to require that a beneficiary must be under a plan of care, established by a physician. In accordance with section 1861(iii)(1)(B) of the Act, a physician is defined at section 1861(r)(1) of the Act, as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. We propose to require at § 414.1515, that the plan of care must contain those items listed in § 486.520(b). In addition to the type of home infusion therapy services to be furnished, the physician's orders for services in the plan of care must also specify at what frequency the services will be furnished, as well as the healthcare professional that will furnish each of the ordered services. We are soliciting comments on the proposed conditions for payment, which include patient eligibility and plan of care requirements.

c. Qualified Home Infusion Therapy Suppliers and Professional Services

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 the pharmacy, physician, or provider of services or supplier furnishes items or services. The qualified home infusion therapy supplier 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 organization designated by the Secretary; and meet such other requirements as the Secretary determines appropriate. In accordance with this section of the Act, 42 CFR part 486, subpart I, establishes the requirements that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program. These requirements provide a framework for CMS to approve home infusion therapy accreditation organizations in order for them to approve Medicare certification of qualified home infusion therapy suppliers. Section 488.1010 sets forth the requirements that accrediting organizations must meet in order to

223&ncdver=2&DocID=280.14&SearchType=Advanced&bc=IAAAABAAAAAA&.

demonstrate that their substantive accreditation requirements are sufficient for certification of a Medicare qualified home infusion therapy supplier. And finally, § 486.525 sets out the services furnished by a qualified home infusion therapy supplier which are: Professional services, including nursing services; training and education; and remote monitoring and monitoring services. Importantly, neither the statute, nor the health and safety standards and accreditation requirements require the qualified home infusion therapy supplier to furnish the pump, home infusion drug, or related pharmacy services. The infusion pump, drug, and other supplies, including the services required to furnish these items (that is, the compounding and dispensing of the drug) remain covered under the DME benefit.

In accordance with section 1861(iii)(1) of the Act, the CY 2019 HH PPS proposed rule described the professional and nursing services, as well as the training, education, and monitoring services included in the payment to a qualified home infusion therapy supplier for the provision of home infusion drugs (83 FR 32467). We did not specifically enumerate a list of ''professional services'' in order to avoid limiting services or the involvement of providers of services or suppliers that may be necessary in the care of an individual patient. However, it is important to note that, under section 1862(a)(1)(A) of the Act, no payment can be made for Medicare services under Part B that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, unless explicitly authorized by statutes (such as vaccines).

Payment to a qualified home infusion therapy supplier is for an infusion drug administration calendar day in the individual's home, which, in accordance with section 1834(u)(7)(E) of the Act, refers to payment only for the date on which professional services were furnished to administer such drugs to such individual. Ultimately, the qualified home infusion therapy supplier is the entity responsible for furnishing the necessary services to administer the drug in the home and, as we noted in the CY 2019 HH PPS final rule (83 FR 56581), ''administration'' refers to the process by which the drug is entering the patient's body. Therefore, it is necessary for the qualified home infusion therapy supplier to be in the patient's home, on occasions when the drug is being administered in order to provide an accurate assessment to the physician responsible for ordering the home infusion drug and services. The services provided would include patient evaluation and assessment; training and education of patients and their caretakers, assessment of vascular access sites and obtaining any necessary bloodwork; and evaluation of medication administration. However, visits made solely for the purposes of venipuncture on days where there is no administration of the infusion drug would not be separately paid because the single payment includes all services for administration of the drug. Payment for an infusion drug administration calendar day is a bundled payment, which reflects not only the visit itself, but any necessary follow-up work (which could include visits for venipuncture), or care coordination provided by the qualified home infusion therapy supplier. Any care coordination, or visits made for venipuncture, provided by the qualified home infusion therapy supplier that occurs outside of an infusion drug administration calendar day would be included in the payment for the visit (83 FR 56581).

Additionally, section 1861(iii)(1)(B) of the Act requires that the patient be under a plan of care established and periodically reviewed by a physician, in coordination with the furnishing of home infusion drugs. The physician is responsible for ordering the reasonable and necessary services for the safe and effective administration of the home infusion drug, as indicated in the patient plan of care. In accordance with this section, the physician is responsible for coordinating the patient's care in consultation with the DME supplier furnishing the home infusion drug. We recognize that collaboration between the ordering physician and the DME supplier furnishing the home infusion drug is imperative in providing safe and effective home infusion. Payment for physician services, including any home infusion care coordination services, are separately paid to the physician under the PFS and are not covered under the home infusion therapy benefit. However, payment under the home infusion therapy benefit to eligible home infusion therapy suppliers is for the professional services that inform collaboration between physicians and home infusion therapy suppliers. Care coordination between the physician and DME supplier, although likely to include review of the services indicated in the home infusion therapy supplier plan of care, is paid separately from the payment under the home infusion therapy benefit.

The DME Quality Standards require the supplier to review the patient's record and consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s). Follow-up services to the beneficiary and/or caregiver(s), must be consistent with the type(s) of equipment, item(s) and service(s) provided, and include recommendations from the prescribing physician or healthcare team member(s).[215] Additionally, DME suppliers are required to communicate directly with patients regarding their medications. As described in Chapter 5 of the Medicare Program Integrity Manual: Items and Services Having Special DME Review Considerations, section 5.2.8, DME suppliers are required to contact the beneficiary prior to dispensing a refill to the original order. This is done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order.[216]

Additionally, the ordering physician can bill separately for physicians' services such as Chronic Care Management (CCM) and Remote Patient Monitoring codes under the PFS for care planning and coordination of home infusion therapy services. CCM services are typically provided outside of face-to-face patient visits, and focus on characteristics of advanced primary care such as a continuous relationship with a designated member of the care team; patient support for chronic diseases to achieve health goals; 24/7 patient access to care and health information; receipt of preventive care; patient and caregiver engagement; and timely sharing and use of health information.[217] Remote patient monitoring services, including telephone evaluation and management services by a physician, or brief virtual check-ins, can also be billed under the PFS. In general, when communication technology-based services originate from a related evaluation and management (E/M) visit provided within the previous 7 days by the same physician or other qualified health care professional, this service is considered bundled into that previous E/M visit and would not be separately billable.

[215] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf.*

[216] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf.*

[217] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf.*

However, physicians can bill separately for remote monitoring services after an initial face-to-face visit. Billing for this service requires at least 30 minutes of physician time and includes the collection and interpretation of data. Beginning January 1, 2019, Medicare now also pays separately for set-up, interpretation, and transmission of data collected remotely. Additionally, virtual check-in services are billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology to assess whether the patient's condition necessitates an office visit, and can be billed in cases where the check-in service does not lead to an office visit, as there is no office visit with which the check-in service can be bundled.[218]

In summary, the qualified home infusion therapy supplier is responsible for the reasonable and necessary services related to the administration of the home infusion drug in the individual's home. These services may require some degree of care coordination or monitoring outside of an infusion drug administration calendar day; however, these services are built into the bundled payment. Care coordination furnished by the DME supplier, who is responsible for furnishing the equipment and supplies, including the home infusion drug, is required and paid for under the DME benefit. Care coordination furnished by the physician who establishes the plan of care is separately billable under the PFS.

d. Home Infusion Therapy and the Interaction With Home Health

Because a qualified home infusion therapy supplier is not required to become accredited as a Part B DME supplier or to furnish the home infusion drug, and because payment is determined by the provision of services furnished in the patient's home, we acknowledged in the CY 2019 HH PPS proposed rule the potential for overlap between the new home infusion therapy benefit and the home health benefit (83 FR 32469). We stated that a beneficiary is not required to be considered homebound in order to be eligible for the home infusion therapy benefit; however, there may be instances where a beneficiary under a home health plan of care also requires home infusion therapy services. Additionally, because section 5012 of the 21st Century Cures Act amends section 1861(m) of the Act to exclude home infusion therapy from home health services effective on January 1, 2021, we stated that a beneficiary may utilize both benefits concurrently. We solicited feedback on the relationship between the Medicare home health benefit and the home infusion therapy benefit, particularly in instances when a beneficiary meets eligibility requirements for both.

In general, commenters stated concern with the ability of qualified home infusion therapy suppliers to furnish the professional services required under both benefits when care needs overlap. One commenter stated that the benefits effectively do not overlap, as ''each benefit stands independent from the other and covers different treatment and different care.'' Specifically, this commenter stated that home health agencies do not own or operate pharmacies, prepare home infusion drugs, or provide the care coordination necessary to manage drug infusion. Similarly, the commenter stated that home infusion providers are neither certified nor authorized to offer the full array of care services required of a home health agency.

We agree that there are unique services and providers involved in the delivery of care under both the home health benefit and the home infusion therapy benefit. We also recognize that home health agencies and DME suppliers have separate requirements for accreditation and conditions for payment. Likewise, the requirements for home infusion therapy accreditation, set out at 42 CFR part 486, subpart I, are unique to qualified home infusion therapy suppliers. For instance, in order to furnish the services related to the administration of home infusion drugs, a qualified home infusion therapy supplier is not required to meet the Medicare Home Health Conditions of Participation (CoPs) at 42 CFR part 484, unless such supplier is also a Medicare-certified home health agency. Additionally, a qualified home infusion therapy supplier is not required to meet the requirements under the DME Quality and Supplier Standards, unless such supplier is also a Medicare-enrolled DME supplier. Therefore, we would not expect a home health agency that becomes accredited as a qualified home infusion therapy supplier to furnish (or arrange for the furnishing of) the DME, supplies (including the home infusion drug), and related services when a patient is not under a home health plan of care, nor would it be permissible for a DME supplier that becomes accredited as a qualified home infusion therapy supplier to furnish home health services under the Medicare home health benefit. The home health benefit requires that home health agencies arrange for the necessary DME and coordinate home infusion services when a patient is under a home health plan of care. In accordance with the Home Health CoPs at 42 CFR 484.60, the home health agency must assure communication with all physicians involved in the plan of care, as well as integrate all orders and services provided by all physicians and other healthcare disciplines, such as nursing, rehabilitative, and social services.

Furthermore, because both the home health agency and the qualified home infusion therapy supplier furnish services in the individual's home, and may potentially be the same entity, it is necessary to outline the payment process in instances when a beneficiary is utilizing both benefits. We continue to believe that the best process for payment for furnishing home infusion therapy services to beneficiaries who qualify for both benefits is as outlined in the CY 2019 HH PPS proposed rule (83 FR 32469). If a patient receiving home infusion therapy is also under a home health plan of care, and receives a visit that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the home health claim. When the home health agency furnishing home health services is also the qualified home infusion therapy supplier furnishing home infusion services, and a home visit is exclusively for the purpose of furnishing items and services related to the administration of the home infusion drug, the home health agency would submit a home infusion therapy services claim under the home infusion therapy benefit. If the home visit includes the provision of other home health services in addition to, and separate from, home infusion therapy services, the home health agency would submit both a home health claim under the HH PPS and a home infusion therapy claim under the home infusion therapy benefit. However, the agency must separate the time spent furnishing services covered under the HH PPS from the time spent furnishing services covered under the home infusion therapy benefit. DME continues to be excluded from the consolidated billing requirements governing the HH PPS and therefore, the DME services, equipment, and supplies (including the drug and related services) will continue to be paid for outside of the HH PPS. If the qualified home infusion therapy supplier is not the same entity as the home health agency furnishing the home health services, the

[218] *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf.*

home health agency would continue to bill under the HH PPS on the home health claim, and the qualified home infusion therapy supplier would bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

After publishing the CY 2019 HH PPS final rule with comment period, we received correspondence requesting clarification of the relationship between the home health benefit and the furnishing of home infusion therapy services in CYs 2019 and 2020. Specifically, we received questions as to whether an eligible home infusion supplier can furnish home infusion therapy services, and bill for the temporary transitional payment, to the same patient that is under a home health plan of care, where the home health agency is furnishing care unrelated to the home infusion therapy, such as wound care and physical therapy. In response, we posted a ''Frequently Asked Questions'' (FAQs) document to our home infusion therapy web page,[219] relying on the authority of section 1834(u)(7)(G) of the Act (as added by section 50401 of the BBA of 2018), which allows the Secretary to implement the transitional home infusion therapy benefit by program instruction or otherwise, notwithstanding any other provision of law. In this FAQ, we clarified that during the 2-year temporary transitional payment period (CYs 2019 and 2020), home health services covered under the Medicare home health benefit continue to include the in-home services covered under the new home infusion therapy benefit. Therefore, if a patient's home health plan of care includes home infusion therapy services, the costs of such services would be recognized as part of the payment made for the patient's specific Home Health Resource Group (HHRG). The clarification in the FAQs was not intended to, and does not, make any changes to our general policy that, as with any other plan of care service that the HHA cannot provide, if a patient under a home health plan of care requires in-home skilled services needed for the safe and effective administration of a transitional home infusion drug and the home health agency determines it does not have the staff available to furnish those services as home health services under the home health benefit (and cannot provide such services under arrangement), the home health agency should not accept the patient on service or continue to provide other home health services under an existing plan of care. In accordance with the Home Health CoPs at § 484.60 home health agencies can only accept patients for treatment on the reasonable expectation that the home health agency can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence.

We believe the statutory provisions at section 1861(m) of the Act do not allow both home health providers and eligible home infusion suppliers to furnish and bill for home infusion therapy services to beneficiaries under a home health plan of care. Therefore we stated in the CY 2019 HH PPS final rule that home infusion therapy was excluded from home health services beginning in CY 2019. This was intended to convey that *payment* for the separate, transitional home infusion therapy services benefit under section 1834(u)(7) of the Act is excluded from home health services. Sections 5012(c)(3) and (d) of the Cures Act, read together, clearly indicate that home infusion therapy is not excluded from home health services until January 1, 2021. A home health agency may subcontract with an eligible home infusion supplier in CYs 2019 and 2020 to furnish home infusion therapy services to a beneficiary under a home health plan of care; however, such services would be considered home health services and should be billed by the home health agency under the Medicare home health benefit and not the home infusion therapy benefit. In addition, the eligible home infusion supplier cannot bill for such services under the home infusion therapy benefit as such services are covered as home health services under the Medicare home health benefit.

Therefore, for home infusion therapy services furnished in CYs 2019 and 2020, if a patient who is considered homebound and is under a Medicare home health plan of care, the home health agency should continue to furnish the professional services related to the administration of transitional home infusion drugs, in accordance with the Home Health CoPs and other regulations, as home health services. Additionally, the home health agency shall bill for such services as home health services under the Medicare home health benefit. Further, if an eligible home infusion supplier is under contract with a home health agency to provide the necessary home infusion therapy services to a patient under a home health plan of care, such services would be considered home health services and billed by the home health agency under the Medicare home health benefit and not the home infusion therapy benefit. Additionally, the eligible home infusion supplier under contract with the home health agency cannot bill Medicare for the temporary transitional payment but would seek payment from the home health agency. This clarification regarding the relationship between the home health benefit and the home infusion benefit in CYs 2019 and 2020 is not intended to limit access to home infusion therapy services to those beneficiaries receiving home health services under the Medicare home health benefit. Neither the transitional nor the permanent home infusion therapy services benefit require that the beneficiary be under a home health plan of care. Rather, because transitional home infusion therapy services are separately payable beginning January 1, 2019, the receipt of home health services is not necessary in order for a beneficiary to be eligible to receive home infusion therapy services.

2. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy Services

Section 1834(u)(6) of the Act requires that prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) of the Act for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part. We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy options. For example, a physician may verbally discuss the treatment options with the patient during the visit and annotate the treatment decision in the medical records before establishing the infusion therapy plan. Some physicians may also provide options in writing to the patient in the hospital discharge papers or office visit summaries, as well as retain a written patient attestation that all options were provided and considered. Additionally, the frequency of discussing these options could vary based on a routine scheduled visit or according the individual's clinical needs.

We are soliciting comments in the CY 2020 PFS proposed rule regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment

[219] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html.*

options available to his/her patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invite comments in this rule on any additional interpretations of this notification requirement and whether this requirement is already being met under the temporary transitional payment.

D. Proposed Payment Categories and Amounts for Home Infusion Therapy Services for CY 2021

Section 1834(u)(1) of the Act provides the authority for the development of a payment system for Medicare-covered home infusion therapy services. In accordance with section 1834(u)(1)(A)(i) of the Act, the Secretary is required to implement a payment system under which a single payment is made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment under this payment system is for each infusion drug administration calendar day in the individual's home, and requires the Secretary, as appropriate, to establish single payment amounts for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the PFS (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting. Furthermore, such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. This permanent payment system would become effective for home infusion therapy items and services furnished on or after January 1, 2021.

In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment for each infusion drug administration calendar day in the individual's home must be established for types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Furthermore, section 1834(u)(1)(B)(ii) of the Act requires that the payment amount reflect factors such as patient acuity and complexity of drug administration. We believe that the best way to establish a single payment amount that varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, is to group home infusion drugs by J-code into payment categories reflecting similar therapy types. Therefore, each payment category would reflect variations in infusion drug administration services.

Section 1834(u)(7)(C) of the Act established three payment categories, with the associated J-code for each transitional home infusion drug (see Table 28), for the home infusion therapy services temporary transitional payment. Payment category 1 comprises certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including, but not limited to, antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 comprises subcutaneous infusions for therapy or prophylaxis, including, but not limited to, certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

Maintaining the three current payment categories, with the associated J-codes as outlined in section 1834(u)(7)(C) of the Act, utilizes an already established framework for assigning a unit of single payment (per category), accounting for different therapy types, as required by section 1834(u)(1)(A)(ii) of the Act. The payment amount for each of these three categories is different, though each category has its associated single payment amount. The single payment amount (per category) would thereby reflect variations in nursing utilization, complexity of drug administration, and patient acuity, as determined by the different categories based on therapy type. Retaining the three current payment categories would maintain consistency with the already established payment methodology and ensure a smooth transition between the temporary transitional payments and the permanent payment system to be implemented beginning with 2021. Therefore, we propose to carry forward the three temporary transitional payment categories for the home infusion therapy services payment in CY 2021. Table 28 provides the list of J-codes associated with the infusion drugs that fall within each of the payment categories. There are several drugs that are paid for under the transitional benefit but would not be defined as a home infusion drug under the permanent benefit beginning with 2021. As noted previously in this proposed rule, 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 DME. Such term does not include the following: (1) Insulin pump systems; and (2) a self-administered drug or biological on a self-administered drug exclusion list. Hizentra, a subcutaneous immunoglobulin, is not included in this definition of home infusion drugs because it is listed on a self-administered drug (SAD) exclusion list by the MACs. This drug was included as a transitional home infusion drug since the definition of such drug in section 1834(u)(7)(A)(iii) of the Act does not exclude self-administered drugs or biologicals on a SAD exclusion list under the temporary transitional payment. Therefore, although home infusion therapy services related to the administration of Hizentra are covered under the temporary transitional payment, because it is on a SAD exclusion list, services related to the administration of this biological are not covered under the benefit in 2021. Similarly, in accordance with the definition of ''home infusion drug'' as a parenteral drug or biological administered intravenously or subcutaneously, home infusion therapy services related to the administration of Ziconotide and Floxuridine are also excluded, as these drugs are given via intrathecal and intra-arterial routes respectively and therefore do not meet the definition of home infusion drug. Subsequent drugs added to the DME LCD for external infusion pumps, and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be grouped into the appropriate payment category by the DME MACs. Payment category 1 would include any subsequent intravenous infusion drug additions, payment category 2 would include any subsequent subcutaneous infusion drug additions, and payment category 3 would include any subsequent intravenous chemotherapy infusion drug additions.

TABLE 28: INFUSION DRUG J-CODES ASSOCIATED WITH HOME INFUSION THERAPY SERVICE PAYMENT CATEGORIES FOR CY 2021

J-Code	Drug
Category 1	
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J1555 JB*	Injection, immune globulin (cuvitru), 100 mg
J1561 JB*	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB*	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB*	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB*	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

*The JB modifier indicates that the route of administration is subcutaneous.

We are soliciting comments on retaining the three payment categories, as identified in Table 28, in CY 2021.

1. Proposed Payment Amounts

As described previously, section 1834(u)(1)(A)(ii) of the Act requires that the payment amount take into account variation in utilization of nursing services by therapy type. Additionally, section 1834(u)(1)(A)(iii) of the Act provides a limitation that the single payment shall not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. Finally, section 1834(u)(1)(B)(ii) of the Act requires the payment amount to reflect patient acuity and complexity of drug administration.

The language at section 1834(u)(1)(A)(ii) of the Act is consistent with section 1834(u)(7)(B)(iv) of the Act, which establishes a ''single payment amount'' for the temporary transitional payment for an infusion drug administration calendar day. Currently, as set out at section 1834(u)(7)(D) of the Act, each temporary transitional payment category is paid at amounts in accordance with six infusion CPT codes and units of such codes under the PFS. These payment category amounts are set equal to 4 hours of infusion therapy administration services in a physician's office for each infusion drug administration calendar day, regardless of the length of the visit. We stated in the CY 2019 final rule (83 FR 56581) that a ''single payment amount'' means that all home infusion therapy services, which include professional services, including nursing; training and education; remote monitoring; and monitoring, are built into the day on which the services are furnished in the home and the drug is being administered. In other words, payment for an infusion drug administration

calendar day is a bundled payment amount per visit. As such, because payment for an infusion drug administration calendar day under the permanent benefit is also a ''unit of single payment,'' we propose to carry forward the payment methodology as outlined in section 1834(u)(7)(A) of the Act for the temporary transitional payments. We propose to pay a single payment amount for each infusion drug administration calendar day in the individual's home for drugs assigned under each proposed payment category. Each proposed payment category amount would be in accordance with the six infusion CPT codes identified in section 1834(u)(7)(D) of the Act and as shown in Table 29. However, because section 1834(u)(1)(A)(iii) of the Act states that the single payment shall not exceed more than 5 hours of infusion for a particular therapy in a calendar day, we propose that the single payment amount be set at an amount equal to 5 hours of infusion therapy administration services in a physician's office for each infusion drug administration calendar day.

We believe that proposing a single unit of payment equal to 5 hours of infusion therapy services in a physician's office is a reasonable approach to account for the bundled services included under the home infusion therapy benefit, as described previously. We also understand that some patients may require more care coordination or longer visits than other patients, and while the physician payments would account for varying time spent furnishing care for individual patients (both during a visit and outside of a visit) in accordance with the specific PFS codes they bill, payment for an infusion drug administration calendar day is a unit of single payment and would not vary within each category. While the payment amounts do vary between categories to account for differences in therapy type, paying the maximum amount allowed by statute acknowledges the varying care needs of each individual patient within each category. For example, a qualified home infusion therapy supplier furnishing care for a patient receiving a category 2 infusion drug would receive a single payment amount for each infusion drug administration calendar day in the patient's home. However, this payment amount would not reflect the varying degrees of care among individual patients within each category, or from visit to visit for the same patient. And while the payment rates for each of the three payment categories is higher than the home health per-visit nursing rate, the home infusion therapy rates reflect the increased complexity of the professional services provided per category, and as required by law.

Furthermore, furnishing care in the patient's home is fundamentally different from furnishing care in the physician's office. Healthcare professionals cannot achieve the economies of scale in the home that can be achieved in an office setting. As noted previously, the single unit of payment for each of the three categories is a bundled payment, meaning payment is made on the basis of expected costs for clinically-defined episodes of care, where some episodes of care for similar patients with similar care needs cost more than others. While the single unit of payment for the temporary transitional payments was set at 4 hours by law, the payment amount for home infusion therapy services beginning in CY 2021 cannot exceed 5 hours of infusion for a particular therapy. As such, the law provides more latitude for the payment of home infusion therapy services beginning in CY 2021. To ensure that payment for home infusion therapy adequately covers the different patient care needs and level of complexity of services provided, we are proposing that the bundled payment amount for home infusion therapy services furnished on and after January 1, 2021 should be set at the maximum allowed by statute, 5 hours, in order to account for these differences and still remain a unit of single payment.

Setting the payment amounts for each proposed payment category in accordance with the CPT infusion code amounts under the PFS accounts for variation in utilization of nursing services, patient acuity, and complexity of drug administration. CPT codes establish uniformity of the services that fall under each code in order to determine the amount of payment that a practitioner will receive for such services. Medicare PFS valuation of CPT codes uses a combination of the time and complexity used to furnish the service, as well as the amount and value of resources used. Relative value units (RVUs) are calculated for three components used to determine the value of a CPT code. One component, the non-facility practice expense RVU, is based, in part, on the amount and complexity of services furnished by nursing and ancillary clinical staff involved in the procedure or service.[220] The CPT infusion codes under the PFS weight the non-facility practice expense RVUs more heavily than the other two components, which include physician work and malpractice expense.[221] Therefore, the values of the CPT infusion code amounts, in accordance with the different payment categories, reflect variations in nursing utilization, patient acuity, and complexity of drug administration, as they are directly proportionate to the clinical labor involved in furnishing the infusion services in the patient's home.

[220] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096340/.*

[221] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files-Items/RVU19A.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.*

TABLE 29: PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES PAYMENT FOR CY 2021

CPT CODE	DESCRIPTION	UNITS
	CATEGORY 1	
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
	CATEGORY 2	
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
	CATEGORY 3	
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- up to one hour	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- each additional hour	4

The payment methodology outlined previously meets the required payment adjustments, while remaining a single unit of payment. However, we recognize that often the first visit furnished by a home infusion therapy supplier to furnish services in the patient's home may be longer or more resource intensive than subsequent visits. In particular, patients with new diagnoses may require more disease education, instruction on self-monitoring, and support from healthcare professionals. Patients who have not been hospitalized may be starting home infusion therapy without the benefit of having received any training or education prior to discharge. Additionally, considering that hospitals often discharge quickly once outside services are in place, patients who have started infusion therapy in the hospital, may arrive home with central vascular access devices and ambulatory pumps without sufficient education or instruction regarding maintenance or lifestyle changes. This could potentially lead to safety issues or an increase in doctor's office or emergency department visits. Therefore, the single payment amount discussed previously may not adequately compensate for the first patient visit furnished by the qualified home infusion therapy supplier in the patient's home. Section 1834(u)(1)(C) of the Act allows the Secretary discretion to adjust the single payment amount to reflect outlier situations and other factors as the Secretary determines appropriate, in a budget neutral manner. Payment for infusion therapy in the physician's office reflects whether a patient is new or existing, acknowledging that new patients may initially require more time and education. Therefore, we propose increasing the payment amounts for each of the three payment categories for the first visit by the relative payment for a new patient rate over an existing patient rate using the physician evaluation and management (E/M) payment amounts for a given year. Overall this adjustment would be budget-neutral, in accordance with the requirement at section 1834(u)(1)(C)(ii) of the Act, resulting in a small decrease to the payment amounts for any subsequent visits. This would be similar to the LUPA add-on payment under the home health benefit, which is paid for the first LUPA episode in a sequence of adjacent episodes or episodes that occur as the only episode. It is important to note that the first visit payment amount is only issued on the first home visit to initiate home infusion therapy services furnished by the qualified home infusion therapy supplier. Any changes in the plan of care or drug regimen, including the addition of drugs or biologicals that may change the payment category, would not trigger a first visit payment amount. If a patient receiving home infusion therapy services is discharged, the home infusion therapy services claim must show a patient status code to indicate a discharge with a gap of more than 60 days in order to bill a first visit again if the patient is readmitted. This means that upon re-admission, there cannot be a G-code billed for this patient in the past 60 days, and the last G-code billed for this patient must show that the patient had been discharged. A qualified home infusion therapy supplier could bill the first visit payment amount on day 61 for a patient who had previously been discharged from service. We also recognize that many beneficiaries have been receiving services during the temporary transitional payment period, and as a result, many of these patients already have a working knowledge of their pump and may need less start-up time with the nurse during their initial week of visits during the permanent benefit. Therefore, suppliers would not be able to bill for the initial visit amount for those patients who have been receiving services under the temporary transitional payment, and have billed a G-code within the past 60 days. Table 30 shows the E/M visit codes and PFS payment amounts for CY 2019, for both new and existing patients, used to determine the increased payment amount for the first visit. Using the CY 2019 PFS rates, this results in a 60 percent increase in the first visit payment amount and a 3.76 percent decrease in subsequent visit amounts.

TABLE 30: AVERAGE DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS222

New Patient E/M code	PFS Amount	Existing Patient E/M code	PFS Amount	Percent Difference
99201	$46.49	99211	$23.07	102%
99202	$77.48	99212	$25.95	199%
99203	$109.92	99213	$75.32	46%
99204	$166.86	99214	$110.28	51%
99205	$209.75	99215	$147.76	42%
Total	$610.50		$382.38	60%

In summary,we propose that the payment amounts per category, for an infusion drug administration calendar day under the permanent benefit, be in accordance with the six PFS infusion CPT codes and units for such codes, as described in section 1834(u)(7)(D) of the Act; however, we propose to set the amount equivalent to 5 hours of infusion in a physician's office, rather than 4 hours. We also propose increasing the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year, resulting in a small decrease to the payment amounts for the second and subsequent visits, using a budget neutrality factor. Table 31 shows the 5 hour payment amounts (using CY 2019 rates) reflecting the increased payment for the first visit and the decreased payment for all subsequent visits. We plan on monitoring home infusion therapy service lengths of visits, both initial and subsequent, in order to evaluate whether the data substantiates this increase or whether we should re-evaluate whether, or how much, to increase the initial visit payment amount. We are soliciting comments on the proposed CY 2021 payment amounts per category, including the proposed payment equivalent to 5 hours of infusion in a physician's office and increasing the payment amounts for each of the three categories for the first home infusion therapy visit by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year.

TABLE 31: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FOR FIRST AND SUBSEQUENT VISITS

CPT Code	Description	2019 PFS Amount	5-hour Payment – First Visit	5-hour Payment – Subsequent Visits
96365	Ther, Proph,Diag IV/IN infusion 1 hr	$72.80	$257.20 (category 1)	$154.70 (category 1)
96366	Ther, Proph,Diag IV/IN infusion add hr	$21.98		
96369	Sub Q Ther Inf 1 hr	$169.02	$371.94 (category 2)	$223.72 (category 2)
96370	Sub Q Ther Inf add hr	$15.86		
96413	Chemo Inf 1 hr	$143.08	$427.26 (category 3)	$256.99 (category 3)
96415	Chemo Inf add hr	$30.99		

222 This represents the average difference between the physician E/M payment amounts for new versus established patients: (the sum of the initial rates − the sum of the existing rates)/(the sum of the existing rates) = 60%.

E. Required Payment Adjustments for CY 2021 Home Infusion Therapy Services

1. Proposed Home Infusion Therapy Geographic Wage Index Adjustment

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. In the 2019 HH PPS proposed rule (83 FR 32467) we stated that we were considering using the Geographic Practice Cost Indices (GPCIs) to account for regional variations in wages and adjust the payment for home infusion therapy professional services; however, after further analysis and consideration we believe the geographic adjustment factor (GAF) may be a more appropriate option to adjust home infusion therapy payments based on differences in geographic wages.

The GAF is a weighted composite of each PFS locality's work, practice expense (PE), and malpractice (MP) GPCIs and represents the combined impact of the three GPCI components. The GAF is calculated by multiplying the work, PE and MP GPCIs by the corresponding national cost share weight: Work (50.886 percent), PE (44.839 percent), and MP (4.295 percent).[223] The work GPCI reflects the relative costs of physician labor by region. The PE GPCI measures the relative cost difference in the mix of goods and services comprising practice expenses among the PFS localities as compared to the national average of these costs. The MP GPCI measures the relative regional cost differences in the purchase of professional liability insurance (PLI). The GAF is updated at least every 3 years per statute and reflects a 1.5 work GPCI floor for services furnished in Alaska as well as a 1.0 PE GPCI floor for services furnished in frontier states (Montana, Nevada, North Dakota, South Dakota and Wyoming). The GAF is not specific to any of the home infusion drug categories, so the GAF payment rate would equal the unadjusted rate multiplied by the GAF for each locality level, without a labor share adjustment. As such, based on locality, the GAF adjusted payment rate would be calculated using the following formula:

$$Rate_i^{GAF} = GAF * UnadjRate_i$$

We would apply the appropriate GAF value to the home infusion therapy single payment amount based on the site of service of the beneficiary. There are currently 112 total PFS localities, 34 of which are statewide areas (that is, only one locality for the entire state). There are 10 states with 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands are the remaining three localities. Beginning in 2017, California's locality structure was modified to increase its number of localities from 9, under the previous locality structure, to 27 under the new Metropolitan Statistical Area based locality structure defined by the Office of Management and Budget (OMB).

The list of GAFs by locality for this proposed rule is available as a downloadable file at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html.*

We considered other alternatives to using the GAF (as discussed in section VIII.E) such as the hospital wage index (HWI), the GPCI, and using just the practice expense component of the GPCI; however, we are proposing to use the GAF to geographically wage adjust home infusion therapy for CY 2021 and subsequent years. We believe the GAF is the best option for geographic wage adjustment because it is the most operationally feasible. Utilizing the GAF would allow adjustments to be made while leveraging systems that are already in place. There are already mechanisms in place to geographically adjust using the GAF and applying this option would require less system changes. The adjustment would happen on the PFS and be based on the beneficiary zip code submitted on the 837P/CMS–1500 professional and supplier claims form.

Table 32 shows the 2019 rates for the temporary, transitional payment by drug category. Using the 2019 rates for the temporary, transitional payments, we estimate what the adjusted payments rates would be using the GAF. Table 33 shows the distribution of standardized adjusted payment rates for the GAF (sorted by standard deviation). The results indicate the distribution of payment rates center around the unadjusted payment rates when adjusting using the GAF.

TABLE 32: 2019 FEE SCHEDULE FOR TRANSITIONAL PAYMENT

Drug Category	Payment Rate
1 – Anti-infective, cardiovascular, pain, other	$138.75
2 – Immune globulin	$216.59
3 – Chemotherapy	$236.06

[223] *GAF* = (.50886 × Work GPCI) + (.44839 × PE GPCI) + (.04295 × MP GPCI)

TABLE 33: GAF DISTRIBUTION OF STANDARDIZED ADJUSTED PAYMENT RATES

Index	Mean	SD	Min	P10	P25	P50	P75	P90	Max
Drug Category 1									
GAF	138.69	8.49	126.77	129.82	132.45	136.33	144.50	151.02	179.28
Drug Category 2									
GAF	215.99	12.37	197.89	202.21	207.19	213.46	224.92	233.57	279.86
Drug Category 3									
GAF	235.93	15.20	215.68	220.86	225.34	229.35	250.09	259.05	305.01

The GAF is further discussed in the CY 2017 PFS final rule (81 FR 80170). Specific GAF values for each payment locality in past years are posted in Addendum D to this proposed rule and can be found at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.* The final CY 2020 GAF rates will be posted when they become available.

We are proposing that the application of the geographic wage adjustment be budget neutral so there would be no overall cost impact. However, this will result in some adjusted payments being higher than the average and others being lower. In order to make the application of the GAF budget neutral we are going to apply a budget-neutrality factor. If the rates were set for 2020 the budget neutrality factor would be 0.9985. The budget neutrality factor will be recalculated for 2021 in next year's rule using 2019 utilization data from the first year of the temporary transitional payment period. We welcome comments on our proposal to use the GAF to wage adjust the home infusion therapy services payment, and commenter's suggestions on whether a factor other than the GAF should be used.

2. Consumer Price Index

Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections we would increase the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI–U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Accordingly, this may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

F. Other Optional Payment Adjustments/Prior Authorization for CY 2021 Home Infusion Therapy Services

1. Prior Authorization

Section 1834(u)(4) of the Act allows the Secretary discretion, as appropriate, to apply prior authorization for home infusion therapy services. Generally, prior authorization requires that a decision by a health insurer or plan be rendered to confirm health care service, treatment plan, prescription drug, or durable medical equipment is medically necessary.[224] Prior authorization helps to ensure that a service, such as home infusion therapy, is being provided appropriately.

In the 2019 HH PPS proposed rule (83 FR 32469), we solicited comments as to whether and how prior authorization could potentially be used in home infusion. The majority of commenters were concerned that applying prior authorization would risk denying or delaying timely access to needed services, as an expeditious transition of care is clinically and economically important in home infusion. Another commenter stated that a CMS process would be welcome assuming the clinical information required is clearly defined, there is a defined CMS response time that does not prevent timely clinical care, that the process is appropriately limited to higher cost drugs, and once prior authorization has been made, retroactive denial for medical necessity would not be allowed.

Ultimately, we do not consider prior authorization to be appropriate for the home infusion therapy benefit, at this time, as the benefit is contingent on the requirement that a home infusion drug or biological be administered through a Medicare Part B covered pump that is an item of DME. As discussed in section VI.E. of this proposed rule, payment for Medicare home infusion therapy is for services furnished in coordination with the furnishing of the infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps (L33794), with the exception of insulin pump systems or any drugs or biologicals on a self-administered drug exclusion list. Therefore, we believe that prior authorization for home infusion therapy services is not necessary at this time, as services are contingent on the requirements under the DME benefit. We will monitor the provision of home infusion therapy services and revisit the need for prior authorization if issues arise.

2. Payments for High-Cost Outliers for Home Infusion Therapy Services

Section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier situations and other factors as the Secretary determines appropriate. In the 2019 HH PPS proposed rule (83 FR 32467) we requested feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation. We received a comment stating that ''it would be premature to consider outlier payments for home infusion therapy at the outset of the payment system. Given that the scope of covered home infusion therapy services is limited, and CMS is required to adjust the payment amount for patient acuity and complexity of drug administration, there may not be a need for outlier payments.'' We agree with this commenter that high cost outlier payments are not necessary at this time. We plan to monitor the need for such payments and if necessary address outlier situations in future rule making.

G. Billing Procedures for CY 2021 Home Infusion Therapy Services

In the CY 2019 HH PPS proposed rule we discussed billing procedures for home infusion therapy services for CY 2021 and subsequent years (83 FR 32467). We stated that we were considering processing claims for home

[224] *https://www.healthcare.gov/glossary/preauthorization/.*

infusion therapy services submitted on a Part B practitioner claim through the A/B MACs, rather than the DME MACs, given that ''qualified home infusion therapy suppliers'' are not limited to DME suppliers. We recognized that, although a qualified home infusion therapy supplier is not required to furnish DME equipment and supplies, in order for the same supplier to bill for both the home infusion therapy services and the DME equipment and supplies (including the drug), the provider or supplier would need to be enrolled as both a Part B qualified home infusion therapy supplier and as a DME supplier. In these instances, the same supplier would need to submit separate claims to both the A/B MACs and the DME MACs. We solicited comments on whether it is reasonable to require separate claims submissions to both the DME MACs and the A/B MACs for processing.

We received a few comments regarding this billing process, both in support of requiring separate claims submissions through the DME MACs and the A/B MACs. We continue to believe that, as a qualified home infusion therapy supplier is only required to enroll in Medicare as a Part B supplier, and is not required to enroll as a DME supplier, it is more practicable to process home infusion therapy service claims through the A/B MACs and the Multi-Carrier System (MCS) for Medicare Part B claims. DME suppliers, also enrolled as qualified home infusion therapy suppliers, would continue to submit DME claims through the DME MACs; however, they would also be required to submit home infusion therapy service claims to the A/B MACs for processing. Therefore, we plan to require that the qualified home infusion therapy supplier would submit all home infusion therapy service claims on the 837P/CMS–1500 professional and supplier claims form to the A/B MACs. DME suppliers, concurrently enrolled as qualified home infusion therapy suppliers, would need to submit one claim for the DME, supplies, and drug on the 837P/CMS–1500 professional and supplier claims form to the DME MAC and a separate 837P/CMS–1500 professional and supplier claims form for the professional services to the A/B MAC. Because the home infusion therapy services are contingent upon a home infusion drug J-code being billed, home infusion therapy suppliers must ensure that the appropriate drug associated with the visit is billed with the visit or no more than 30 days prior to the visit. Additionally, we plan to add the home infusion G-codes to the PFS, incorporating the required annual and geographic wage adjustments. Home infusion therapy suppliers would include a modifier on the appropriate G-code to differentiate the first visit from all subsequent visits, as well as a modifier to indicate when a patient has been discharged from service. This would be necessary in order for the qualified home infusion therapy supplier to bill for the first visit payment amount for a patient who had previously received home infusion therapy services in order to demonstrate a gap of more than 60 days between a discharge and the start of subsequent home infusion therapy services. We will issue a Change Request (CR) providing more detailed instruction regarding billing and policy information for home infusion therapy services, which is expected upon release of the CY 2020 final rule.

VII. 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.

In section V. of this proposed rule, we propose changes and updates to the HH QRP. We believe that the burden associated with the HH QRP proposals is the time and effort associated with data collection and reporting. As of February 1, 2019, there are approximately 11,385 HHAs reporting quality data to CMS under the HH QRP. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/2017/may/oes_nat.htm*). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 34.

TABLE 34: U.S. BUREAU OF LABOR STATISTICS' MAY 2017 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$35.36	$35.36	$70.72
Physical therapists (PT)	29-1123	$42.34	$42.34	$84.68
Speech-Language Pathologists (SLP)	29-1127	$38.35	$38.35	$76.70
Occupational Therapists (OT)	29-1122	$40.69	$40.69	$81.38

As discussed in section V.D. of this proposed rule, we are proposing to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP under our measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm. Additionally, we are proposing to remove OASIS item M1242. Removing M1242 will result in a decrease in burden of 0.3 minutes of clinical staff time to report data at start of care (SOC), 0.3 minutes of clinical staff time to report data at resumption of care (ROC) and 0.3 minutes of clinical staff time to report data at Discharge.

As discussed in section V.E. of this proposed rule, we are proposing to adopt two new measures: (1) Transfer of Health Information to Provider—Post-Acute Care (PAC); and (2) Transfer of Health Information to Patient—Post-Acute Care (PAC), beginning with the CY 2022 HH QRP. We estimate the data elements for the proposed Transfer of Health Information quality measures will take 0.6 minutes of clinical staff time to report data at Discharge and 0.3 minutes of clinical staff time to report data at Transfer of Care (TOC).

In section V.G. of this proposed rule, we are proposing to collect standardized patient assessment data beginning with the CY 2022 HH QRP. We estimate the proposed SPADEs will take 10.05 minutes of clinical staff time to report data at SOC, 9.15 minutes of clinical staff time to report at ROC, and 11.25 minutes of clinical staff time to report data at Discharge.

We estimate that there would be a net increase in clinician burden per OASIS assessment of 9.75 minutes at SOC, 8.85 minutes at ROC, 0.3 minutes at TOC, and 11.55 minutes at Discharge as a result of all of the HH QRP proposals in this proposed rule.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2018 show that the SOC/ROC OASIS is completed by RNs (approximately 84.5 percent of the time), PTs (approximately 15.2 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of $72.90, inclusive of fringe benefits, using the hourly wage data in Table 34. Individual providers determine the staffing resources necessary.

Table 35 shows the total number of OASIS assessments submitted by HHAs in CY 2018 and estimated burden at each time point.

TABLE 35: CY 2018 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time Point	CY 2018 Assessments Completed	Estimated Burden ($)
Start of Care	6,573,010	$77,865,519.71
Resumption of Care	1,113,156	$11,969,488.18
Follow-up	2,067,257	0
Transfer of Care	2,021,383	$736,794.10
Death at Home	42,550	0
Discharge from Agency	5,652,757	$79,326,552.17
TOTAL	**17,470,113**	$169,898,354.17

* Estimated Burden ($) at each Time-Point = (# CY 2018 Assessments Completed) x (clinician burden [min]/60) x ($72.90 [weighted clinician average hourly wage]).

Based on the data in Table 35, for the 11,385 active Medicare-certified HHAs in February 2019, we estimate the total average increase in cost associated with changes to the HH QRP at approximately $14,923.00 per HHA annually, or $169,898,354.17 for all HHAs annually. This corresponds to an estimated increase in clinician burden associated with proposed changes to the HH QRP of approximately 204.7 hours per HHA annually, or 2,330,567.3 hours for all HHAs annually. This estimated increase in burden will be accounted for in the information collection under OMB control number 0938–1279.

VIII. 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 requires 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.

Sections 1895(b)(2) and 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.

2. HHVBP

The HHVBP Model applies a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

3. HH QRP

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.

4. Home Infusion Therapy

Section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act, requires the Secretary to establish a home infusion therapy services payment system under Medicare. Under this payment system a single payment would be made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the Physician Fee Schedule (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted by a geographic wage index. Finally, section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier payments and other factors as deemed appropriate by the Secretary, and are required to be made in a budget neutral manner. This payment system would become effective for home infusion therapy items and services furnished on or after January 1, 2021.

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 temporary transitional payment for 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.B. of this proposed rule), the Secretary established three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act. This rule would continue this categorization for services furnished during CY 2020 for codes and units of such codes, determined without application of the geographic adjustment.

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. Given that we note the follow costs associated with the provisions of this proposed rule:

- A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

The net transfer impact related to the changes in payments under the HH PPS for CY 2020 is estimated to be $250 million (1.3 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the proposed 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.

- HHVBP—The savings impacts related to the HHVBP Model as a whole are estimated at $378 million for CYs 2018 through 2022. We do not believe the proposal in this proposed rule would affect the prior estimate.

- HH QRP—The cost impact for HHA's related to proposed changes to the HH QRP are estimated at $169.9 million.

- Home Infusion Therapy—The CY 2020 cost impact related to the routine updates to the temporary transitional payments for home infusion therapy in CY 2020 is estimated to be less than $1 million in either an increase or a decrease in payments to home infusion therapy suppliers, depending on the final payment rates under the physician fee schedule for CY 2020. The cost impact in CY 2021 related to the implementation of the permanent home infusion therapy benefit is estimated to be a $3 million reduction in payments to home infusion therapy suppliers (using the CY 2019 physician fee schedule payment amounts as the 2020 physician fee schedule amounts were not available at the time of rulemaking).

C. Anticipated Effects

1. HH PPS

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 and home infusion therapy suppliers 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 proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs and home infusions therapy suppliers. Therefore, the Secretary has determined that this HH PPS proposed 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 603 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 will 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 2019, 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 proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

2. HHVBP

Under the HHVBP Model, the first payment adjustment was applied in CY 2018 based on PY 1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY 5 (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 CYs 2017, 2018, and 2019 HH PPS final rules, 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, 82 FR 51751, and 83 FR 56593, respectively). We do not believe the proposal in this proposed rule would affect the prior estimate.

3. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, 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 reviewers of this year's proposed rule would be the similar to the number of commenters on last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed 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 proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 3.53 hours for the staff to review half of this proposed rule, which consists of approximately 105,837 words. For each HHA that reviews the rule, the estimated cost is $386.04 (3.53 hours × $109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is $442,015.80 ($386.04 × 1,145 reviewers). For purposes of this estimate, the number of anticipated reviewers in this year's rule is equivalent to the number of commenters on the CY 2019 HH PPS proposed rule.

D. Detailed Economic Analysis

1. HH PPS

This rule proposes updates to Medicare payments under the HH PPS for the CY 2020. This rule also implements a change in the case-mix adjustment methodology for home health periods of care beginning on and after January 1, 2020 and implements the change in the unit of payment from 60-day episodes to 30-day periods. These changes are made in a budget-neutral manner. The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. 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 2018. 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.

Table 36 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2018 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2018. The first column of Table 36 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 2020 wage index. The fourth column shows the payment effects of the CY 2020 rural add-on payment provision in statute. The fifth column shows the effects of the implementation of the PDGM case-mix methodology for CY 2020. The sixth column shows the payment effects of the CY 2020 home health payment update percentage as required by section 53110 of the BBA of 2018. And the last column shows the combined effects of all the policies proposed in this rule.

Overall, it is projected that aggregate payments in CY 2020 would increase by 1.3 percent. As illustrated in Table 36, 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 2020 wage index, the extent to which HHAs are affected by changes in case-mix weights between the current 153-group case-mix model and the case-mix weights under the 432-group PDGM, 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 36: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2020

	Number of Agencies	CY 2020 Wage Index	CY 2020 Rural Add-On	CY 2020 Case-Mix Weights (PDGM)	CY 2020 HH Payment Update Percentage	Total
All Agencies	**10,124**	**0%**	**-0.2%**	**0.0%**	**1.5%**	**1.3%**
Facility Type and Control						
Free-Standing/Other Vol/NP	1,009	-0.2%	-0.1%	2.7%	1.5%	3.9%
Free-Standing/Other Proprietary	8,092	0.0%	-0.1%	-1.1%	1.5%	0.2%
Free-Standing/Other Government	230	-0.2%	-0.4%	1.9%	1.5%	2.8%
Facility-Based Vol/NP	561	-0.1%	-0.2%	3.5%	1.5%	4.7%
Facility-Based Proprietary	62	0.2%	-0.3%	2.9%	1.5%	4.2%
Facility-Based Government	170	0.4%	-0.4%	4.0%	1.5%	5.4%
Subtotal: Freestanding	9,331	-0.1%	-0.1%	-0.3%	1.5%	1.0%
Subtotal: Facility-based	793	0.0%	-0.2%	3.5%	1.5%	4.8%
Subtotal: Vol/NP	1,570	-0.2%	-0.1%	2.9%	1.5%	4.1%
Subtotal: Proprietary	8,154	0.0%	-0.2%	-1.1%	1.5%	0.2%
Subtotal: Government	400	0.2%	-0.4%	3.1%	1.5%	4.4%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	250	-0.3%	-0.8%	3.8%	1.5%	4.3%
Free-Standing/Other Proprietary	810	0.2%	-0.7%	3.7%	1.5%	4.7%
Free-Standing/Other Government	154	0.1%	-0.8%	0.0%	1.5%	0.8%
Facility-Based Vol/NP	249	0.6%	-0.8%	3.3%	1.5%	4.6%
Facility-Based Proprietary	32	0.3%	-0.8%	10.6%	1.5%	11.6%
Facility-Based Government	129	0.3%	-0.8%	4.5%	1.5%	5.5%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	759	-0.2%	0.0%	2.6%	1.5%	3.8%
Free-Standing/Other Proprietary	7,282	-0.1%	-0.1%	-1.8%	1.5%	-0.4%
Free-Standing/Other Government	76	-0.4%	0.0%	3.5%	1.5%	4.6%

	Number of Agencies	CY 2020 Wage Index	CY 2020 Rural Add-On	CY 2020 Case-Mix Weights (PDGM)	CY 2020 HH Payment Update Percentage	Total
Facility-Based Vol/NP	312	-0.2%	-0.1%	3.5%	1.5%	4.8%
Facility-Based Proprietary	30	0.2%	-0.1%	-0.9%	1.5%	0.6%
Facility-Based Government	41	0.4%	-0.1%	3.6%	1.5%	5.4%
Facility Location: Urban or Rural						
Rural	1,624	0.2%	-0.7%	3.7%	1.5%	4.7%
Urban	8,500	-0.1%	-0.1%	-0.5%	1.5%	0.8%
Facility Location: Region of the Country (Census Region)						
New England	351	-0.7%	-0.1%	2.4%	1.5%	3.1%
Mid Atlantic	466	-0.2%	-0.1%	3.0%	1.5%	4.2%
East North Central	1,890	-0.1%	-0.1%	-0.8%	1.5%	0.4%
West North Central	680	0.5%	-0.3%	-4.2%	1.5%	-2.5%
South Atlantic	1,605	-0.2%	-0.1%	-5.3%	1.5%	-4.1%
East South Central	410	0.1%	-0.4%	0.6%	1.5%	1.8%
West South Central	2,567	0.2%	-0.2%	4.5%	1.5%	6.0%
Mountain	685	0.1%	-0.1%	-5.8%	1.5%	-4.3%
Pacific	1,426	0.0%	0.0%	3.8%	1.5%	5.3%
Outlying	44	-0.5%	-0.3%	10.5%	1.5%	11.3%
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,747	0.2%	-0.1%	2.1%	1.5%	3.6%
100 to 249	2,157	0.1%	-0.1%	0.9%	1.5%	2.4%
250 to 499	2,127	0.1%	-0.1%	0.6%	1.5%	2.0%
500 to 999	1,629	0.0%	-0.2%	-0.4%	1.5%	0.9%
1,000 or More	1,464	-0.1%	-0.2%	-0.2%	1.5%	1.1%

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018 for which we had a linked OASIS assessment.

[1] The CY 2020 home health payment update percentage reflects the home health payment update of 1.5 percent as described in section III.F.1 of this proposed rule.

Notes: The "PDGM" is the 30-day version of the model with no behavioral assumptions applied. This analysis omits 284,404 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 24 periods were excluded with missing NRS weights, and 2,607 periods with a missing urban/rural indicator. The standard 30-day payment amount used to achieve impact neutrality incorporates three behavioral assumptions: (1) that 1/3 of LUPAs 1-2 visits away from the LUPA threshold would receive extra visits and become case-mix adjusted; (2) that among available diagnoses the code leading to the highest payment clinical grouping classification would be designated as the principal diagnosis for clinical grouping; and (3) comorbidity level would be assigned by including comorbidities appearing on HHA claims and not just the OASIS.

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

2. HHVBP

As discussed in section IV. of this proposed rule, for the HHVBP Model, we are proposing to publicly report performance data for PY 5 (CY 2020) of the Model. This proposal would not affect our analysis of the distribution of payment adjustments for PY 5 as presented in the CY 2019 HH PPS final rule. Therefore, we are not providing a detailed analysis.

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. For the CY 2019 payment determination, 1,286 of the 11,444 active Medicare-certified HHAs, or approximately 11.2 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 2020 payment determination.

As discussed in section V.D. of this proposed rule, we are proposing to remove one measure beginning with the CY 2022 HH QRP. The measure we are proposing to remove is Improvement in Pain Interfering with Activity Measure (NQF #0177). As discussed in section V.E. of this proposed rule, we are proposing to add two measures beginning with the CY 2022 HH QRP. The two measures we are proposing to adopt are: (1) Transfer of Health Information to Provider–Post-Acute Care; and (2) Transfer of Health Information to Patient–Post-Acute Care. As discussed in section V.G. of this proposed rule, we are also proposing to collect standardized patient assessment data beginning with the CY 2022 HH QRP. Section VII. of this proposed rule provides a detailed description of the net increase in burden associated with these proposed changes. We have estimated this associated burden beginning with CY 2021 because HHAs will be required to submit data beginning with that calendar year. The cost impact related to OASIS item collection as a result of the changes to the HH QRP is estimated to be a net increase of approximately $169.9 million in annualized cost to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2021.

4. Home Infusion Therapy Services Payment

a. Home Infusion Therapy Services Temporary Transitional Payment

At the time of publication of this proposed rule, the CY 2020 PFS payment rates were not available, therefore we are unable to estimate whether the impact in CY 2020 would result in an increase or decrease in overall payments for home infusion therapy services receiving temporary transitional payments. However, we estimate the impact due to the updated payment amounts for furnishing home infusion therapy services, as determined under the physician fee schedule established under section 1848 of the Act, may result in up to a $1 million increase/decrease in payments for CY 2020.

b. Home Infusion Therapy Services Payment for CY 2021 and Subsequent Years

The following analysis applies to payment for home infusion therapy as set forth in section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114–255), and accordingly, describes the preliminary impact for CY 2021 only. We should also note that as payment amounts are contingent on the Physician Fee Schedule (PFS) rates, this impact analysis will be affected by whether rates increase or decrease in CY 2020. At the time of publication these rates were not available, therefore we used the CY 2019 PFS payment rates for the purpose of this analysis. We used CY 2018 claims data to identify beneficiaries with DME claims containing 1 of the 37 HCPCS codes identified on the DME LCD for External Infusion Pumps (L33794), excluding drugs that are statutorily excluded from coverage under the permanent home infusion therapy benefit. These include drugs and biologicals listed on self-administered drug exclusion lists and drugs administered by routes other than intravenous or subcutaneous infusion. Because we do not have complete data for CY 2019 (the first year of the temporary transitional payments), we used the visit assumptions identified in the CY 2019 HH PPS final rule. We calculated the total weeks of care, which is the sum of weeks of care across all beneficiaries found in each category (as determined from the 2018 claims). Weeks of care for 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 and assumed 1 visit per month, or 12 visits per year. And finally, we assumed 2 visits for the initial week of care, with 1 visit per week for all subsequent weeks in order to estimate the total visits of care per category. For this analysis, we did not factor in an increase in beneficiaries receiving home infusion therapy services due to switching from physician's offices or outpatient centers. Because home infusion therapy services under Medicare are contingent on utilization of the DME benefit, we anticipate utilization will remain fairly stable and that there would be no significant changes in the settings of care where current infusion therapy is provided. We will continue to monitor utilization to determine if referral patterns change significantly once the permanent benefit is implemented in CY 2021. Table 37 reflects the estimated wage-adjusted beneficiary impact, representative of a 4-hour payment rate, compared to a 5-hour payment rate, excluding statutorily excluded drugs and biologicals. Column 3 represents the percent change from the estimated CY 2019 payment under the temporary transitional payment to the estimated CY 2021 payment after applying the GAF wage adjustment. Column 4 represents the percent change from the estimated CY 2021 payment after applying the GAF wage adjustment index and the 5 hour payment rate to the estimated payment after removing the statutorily excluded drugs. Column 5 represents the percent change from the estimated CY 2021 payment after applying the GAF wage adjustment to the estimated CY 2021 payment after applying the 5-hour payment rate (prior to removing statutorily excluded drugs and biologicals). Overall, we estimate a 4.3 percent decrease ($3 million) in payments to home infusion therapy suppliers in CY 2021.

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TABLE 37: ESTIMATED IMPACTS FOR HOME INFUSION THERAPY SERVICES, CY 2021

	Number of Beneficiaries	CY 2021 Wage Adjustment (GAF)	CY 2021 Statutorily Excluded Drugs	CY 2021 Payment Proposal	Total
All Beneficiaries	18,290	0.0%	-16.4%	12.1%	-4.3%
Beneficiary Location: Urban or Rural					
Urban	15,144	0.8%	-16.7%	12.1%	-3.8%
Rural	3,146	-3.9%	-14.6%	11.9%	-6.6%
Beneficiary Location: Region of the Country (Census Division)					
New England	747	4.2%	-22.8%	12.4%	-6.2%
Mid-Atlantic	3,369	4.5%	-6.9%	13.4%	10.9%
East North Central	2,405	-2.5%	-12.9%	12.4%	-2.9%
West North Central	1,336	-4.5%	-18.9%	11.2%	-12.2%
South Atlantic	4,703	-0.8%	-19.7%	11.6%	-8.8%
East South Central	1,227	-7.1%	-22.5%	10.5%	-19.0%
West South Central	1,809	-4.1%	-15.4%	11.6%	-7.9%
Mountain	959	-1.4%	-28.8%	10.7%	-19.5%
Pacific	1,718	6.4%	-19.9%	12.6%	-0.9%
Other	17	0.1%	-0.1%	13.2%	13.1%
Payment Category					
BBA Category 1	6,055	0.0%	-0.1%	15.9%	15.8%
BBA Category 2*	7,322	-0.3%	-48.6%	7.3%	-41.6%
BBA Category 3	4,913	0.2%	-0.1%	13.1%	13.2%

Source: CY 2018 Medicare DME claims data as of March, 2018 containing HCPCS codes equal to one of the 37 codes listed in the BBA of 2018.

*Decrease due to exclusion of Hizentra.

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

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E. Alternatives Considered

1. HH PPS

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 as the BBA of 2018 requires these changes to be implemented on January 1, 2020. 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 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.

We did consider alternatives to complete RAP elimination by CY 2021. Specifically, considered a RAP phase-out over 2 years instead of the proposed 1 year (that is, complete elimination of RAPs by CY 2022) because we believed that additional time would be needed for HHAs to appropriately align their systems with the new policy. However, we chose to propose this change in CY 2020 due to imminent program integrity concerns that have shown increasing amounts of fraudulent activity due to the current RAP policy. We also considered different time frames for the submission of the NOA, including a 7 day timeframe in which to submit a timely-filed NOA. However, to be consistent with similar requirements in other settings (for example, hospice where the NOE must be submitted within 5 calendar days), we believe the 5 day timely-filing requirement would

ensure that the Medicare claims processing system is alerted to mitigate any overpayments for services that should be covered under the home health benefit.

2. HHVBP

With regard to our proposal to publicly report on the CMS website the CY 2020 (PY 5) Total Performance Score (TPS) and the percentile ranking of the TPS for each competing HHA that qualifies for a payment adjustment in CY 2020, we also considered not making this Model performance data public, and whether there was any potential cost to stakeholders and beneficiaries if the data were to be misinterpreted. However, we believe that providing definitions for the HHVBP TPS and the TPS Percentile Ranking methodology would address any such concerns by ensuring the public understands the relevance of these data points and how they were calculated. We also considered the financial costs associated with our proposal to publicly report HHVBP data, but do not anticipate such costs to CMS, stakeholders or beneficiaries, as CMS already calculates and reports the TPS and TPS Percentile Ranking in the Annual Reports to HHAs. As discussed in section IV. of this proposed rule, we believe the public reporting of such data would further enhance quality reporting under the Model by encouraging participating HHAs to provide better quality of care through focusing on quality improvement efforts that could potentially improve their TPS. In addition, we believe that publicly reporting performance data that indicates overall performance may assist beneficiaries, physicians, discharge planners, and other referral sources in choosing higher-performing HHAs within the nine Model states and allow for more meaningful and objective comparisons among HHAs on their level of quality relative to their peers.

3. HH QRP

We believe that removing the Pain Interfering with Activity Measure (NQF #0177) from the HH QRP beginning with the CY 2022 HH QRP would reduce negative unintended consequences. We are proposing the removal of the measure under Meaningful Measures Initiative measure removal Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm. We considered alternatives to this measure and no appropriate alternative measure is ready at this time. Out of an abundance of caution to potential harm from over-prescription of opioid medications inadvertently driven by this measure, we have determined that removing the current pain measure is the most appropriate proposal.

The proposed adoption of two transfer of health information process measures is vital to satisfying section 1899B(c)(1)(E)(ii) of the Act, which requires that the quality measures specified by the Secretary include measures with respect to the quality measure domain of accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual when the individual transitions from a PAC provider to another applicable setting. We believe adopting these measures best addresses the requirements of the IMPACT Act for this domain. We considered not adopting these proposals and doing additional analyses for a future implementation. This approach was not viewed as a viable alternative because of the extensive effort invested in creating the best measures possible and failure to adopt measures in the domain of transfer of health information puts CMS at risk of not meeting the legislative mandate of the IMPACT Act.

Collecting and reporting standardized patient assessment data under the HH QRP is required under section 1899B(b)(1) of the Act. We have carefully considered assessment items for each of the categories of assessment data and believe these proposals best address the requirements of the Act for the HH QRP. The proposed SPADEs are items that received additional national testing after they were proposed in the CY 2018 HH PPS proposed rule (82 FR 35354 through 35371) and more extensively vetted. These items have been carefully considered and the alternative of not proposing to adopt standardized patient assessment data will result in CMS not meeting our legislative mandate under the IMPACT Act.

4. Home Infusion Therapy

a. Home Infusion Therapy Services Temporary Transitional Payment

We did not consider alternatives to updating the home infusion therapy services temporary transitional payment rates for CY 2020 because section 1834(u)(7)(D) of the Act requires the Secretary to pay eligible home infusion suppliers for home infusion therapy services at amounts equal to the amounts determined under the physician fee schedule for services furnished during the year for codes and units of such codes with respect to drugs included in payment categories as outlined in section 1834(u)(7)(C) of the Act, determined without application of the geographic wage adjustment.

b. Home Infusion Therapy Services Payment for CY 2021 and Subsequent Years

We did not consider alternatives to proposing the home infusion therapy services payment system for CY 2021 in the CY 2020 HH PPS proposed rule, given that qualified home infusion therapy suppliers would need ample time to understand and implement the payment policies and billing procedures related to the new payment system.

For the CY 2020 HH PPS proposed rule, we did consider three alternatives to the payment proposals articulated in section VI.D. of this proposed rule. We considered proposing a payment methodology that maintains the three payment categories and PFS codes; but that pays per amount and per unit for the current PFS infusion codes, up to 5 hours, meaning we would not set the payment amount to a base amount of 5 hours of infusion. We would utilize two existing home infusion codes for billing, which would then correspond with the PFS code amounts per hour. Suppliers would bill code 99601 (Home infusion/specialty drug administration, per visit (up to 2 hours)), which would correspond to the first 2 hours of the visit, after which suppliers would bill code 99602 (Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour), up to 3 hours. We would set the minimum payment amount equal to 2 hours of infusion in a physician's office; however, in analyzing CY 2018 physician office (carrier) claims we found that the time required for most infusion services is about an hour. Only 25 to 30 percent of the time, physicians billed for 2 hours of care and the service almost never extended to exceed 2 hours. Nonetheless, we did not propose this option in order to ensure that suppliers are paid appropriately for services provided outside of an infusion drug administration calendar day, and that patients are assured the full scope of services under the home infusion therapy services benefit, which includes remote monitoring.

We also considered proposing to carry forward the payment methodology as outlined in section 50401 of the BBA of 2018, using the current payment categories and PFS infusion code amounts and units for such codes, and setting payment equal to 4 hours of infusion in the physician's office. This methodology would be consistent with the current payment methodology for the temporary transitional payment, and

would not require significant changes in billing procedures. Additionally, the three payment categories would reflect therapy type and complexity of drug administration, as required under section 1834(u)(1)(B) of the Act. This payment methodology is similar to the proposed payment rates; however, setting payment equal to 5 hours of infusion in the physician's office is more in alignment with the language at section 1834(u)(1)(A)(iii) of the Act, which sets the maximum payment amount at 5 hours of infusion for a particular therapy in a calendar day for CY 2021, rather than 4 hours.

And finally, we considered a third alternative which utilizes the 5-hour payment amount, but without the increased payment for the first visit. This option does not recognize the additional time and resources spent during the very first home infusion therapy visit. Increasing the payment rate for the first visit more adequately compensates for the potential increase in visit length as compared to subsequent visits.

Additionally, we considered an alternative to the proposed required geographic wage adjustment articulated in section V1.E. of this proposed rule. Specifically, we considered proposing the pre-floor, pre-reclassified hospital wage index (HWI) that we currently use to wage-adjust payments for both home health and hospice. With the HWI geographic areas are defined using the Core Based Statistical Areas (CBSA) established by the Office of Management and Budget (OMB). The wage index value that is given to a CBSA is the ratio of the area's average hourly wage to the national average hourly wage. The payment for a given region would be determined by applying the wage index value to the labor portion of the single payment amount. Although the HWI is used for other home based services, it presents operational challenges that would make it difficult to use for geographic wage adjustment for home infusion therapy services. These challenges include mapping zip codes to the correct CBSA. In order to utilizing the HWI there would need to be significant system changes to accommodate this option. We do not believe that the benefits of using the HWI outweigh the operational complexity of implementing this option. Also, data analysis showed that payment rates fluctuate more and payments tend to be lower in rural areas when using the HWI. The most negatively affected states using HWI are North Dakota, West Virginia, Alabama, Arkansas, and Louisiana.

In the 2019 proposed home health rule we considered using the Geographic Price Cost Index (GPCI) as the method of wage adjustment (83 FR 32467). The GPCI measures the relative differences in costs of work, practice expense and malpractice in 112 localities compared to the national average. After further analysis we determined the GPCI was not a viable option. GPCI payments are calculated by adjusting the work, practice expense and malpractice relative value units included in the PFS by the corresponding GPCI. The relative value units are then converted into a dollar amount using a conversion factor. The payment for home infusion therapy will be a single payment amount, therefore, a single index is needed to geographically adjust the payment.

Finally, we considered using only the practice expense (PE) GPCI to geographically adjust the home infusion single payment amount. The PE GPCI is designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities compared to the national average of these costs. The PE GPCI comprises four component indices (employee wages; purchased services; office rent; and equipment, supplies, and other miscellaneous expenses). The PE GPCI comprises costs that are similar to home infusion costs. However, we believe that this is not the best method for geographical wage adjustment for several reasons. First, data analysis showed that the PE GPCI is more variable than the GAF. Also, using only the PE GPCI excludes services furnished in Alaska from the 1.0 PE floor and they would also not benefit from the 1.5 work GPCI floor. Finally, the PE GPCI has not been used on its own previously for geographic wage adjustment.

We solicit comments on the alternatives considered for this proposed rule.

F. Accounting Statement and Tables

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 38, we have prepared an accounting statement showing the classification of the transfers and costs associated with the CY 2020 HH PPS provisions of this rule. Table 39 shows the burden to HHA's for submission of OASIS. Table 40 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers for home infusion therapy beginning in CY 2021.

TABLE 38: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2019 TO 2020

Category	Transfers
Annualized Monetized Transfers	$250 million
From Whom to Whom?	Federal Government to HHAs

TABLE 39: 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	+$169.9 million

TABLE 40: ACCOUNTING STATEMENT: PAYMENT FOR HOME INFUSTION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2020 TO 2021

Category	Transfers
Annualized Monetized Transfers	-$3 million
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers

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.'' This proposed rule, if finalized, is considered an E.O. 13771 regulatory action. We estimate the rule generates $169.9 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

H. Conclusion

1. HH PPS for CY 2020

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is an increase of 1.3 percent, or $250 million, in Medicare payments to HHAs for CY 2020. The $250 million increase reflects the effects of the CY 2020 home health payment update percentage of 1.5 percent as required by section 53110 of the BBA of 2018 ($290 million increase), and a 0.2 percent decrease in CY 2020 payments due to the rural add-on percentages mandated by the BBA of 2018 ($40 million decrease).

2. HHVBP

In conclusion, as noted previously for the HHVBP Model, we are proposing to publicly report performance data for PY 5 (CY 2020) of the Model. This proposal would not affect our analysis of the distribution of payment adjustments for PY 5 as presented in the CY 2019 HH PPS final rule.

We estimate there would be no net impact (to include either a net increase or reduction in payments) for this proposed rule in Medicare payments to HHAs competing in the HHVBP Model. However, the overall economic impact of the HHVBP Model is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model.

3. HH QRP

In conclusion, we estimate that the changes to OASIS item collection as a result of the proposed changes to the HH QRP effective on January 1, 2021 would result in a net additional annualized cost of $169.9 million, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2021.

4. Home Infusion Therapy

a. Home Infusion Therapy Services Temporary Transitional Payment for CY 2020

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 may result in up to a $1 million dollar increase/decrease in payments for CY 2020 as determined under the physician fee schedule established under section 1848 of the Act.

b. Home Infusion Therapy Services Payment for CY 2021

In conclusion, we estimate that the net impact of the payment for home infusion therapy services for CY 2021 is approximately $3 million in reduced payments to home infusion therapy suppliers.

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 proposed rule was reviewed by the OMB.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 409.43 is amended by revising paragraph (a) to read as follows:

§ 409.43 Plan of care requirements.

(a) *Contents.* An individualized plan of care must be established and periodically reviewed by the certifying physician.

(1) The HHA must be acting upon a physician plan of care that meets the requirements of this section for HHA services to be covered.

(2) For HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment.

(3) The plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in § 484.60(a) of this chapter that establish the need for such services. All care provided must be in accordance with the plan of care.

* * * * *

■ 3. Section 409.44 is amended by revising paragraph (c)(2)(iii)(C) to read as follows:

§ 409.44 Skilled services requirements.

* * * * *

(c) * * *

(2) * * *

(iii) * * *

(C) The unique clinical condition of a patient may require the specialized skills of a qualified therapist or therapist assistant to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. Where the clinical condition of the patient is such that the

complexity of the therapy services required—

(*1*) Involve the use of complex and sophisticated therapy procedures to be delivered by the therapist or the physical therapist assistant in order to maintain function or to prevent or slow further deterioration of function; or

(*2*) To maintain function or to prevent or slow further deterioration of function must be delivered by the therapist or the physical therapist assistant in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services must be covered.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 4. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 5. Add subpart P to read as follows:

Subpart P—Home Infusion Therapy Services Payment

Conditions for Payment

Sec.

Payment System

Subpart P—Home Infusion Therapy Services Payment

Conditions for Payment

§ 414.1500 Basis, purpose, and scope.

This subpart implements section 1861(iii) of the Act with respect to the requirements that must be met for Medicare payment to be made for home infusion services furnished to eligible beneficiaries.

§ 414.1505 Requirement for payment.

In order for home infusion therapy services to qualify for payment under the Medicare program the services must be furnished to an eligible beneficiary by, or under arrangements with, a qualified home infusion therapy supplier that meets following:

(a) The health and safety standards for qualified home infusion therapy suppliers at § 486.520(a) through (c) of this chapter.

(b) All requirements set forth in §§ 414.1510 through 414.1550.

§ 414.1510 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home infusion therapy services, a beneficiary must meet each of the following requirements:

(a) *Under the care of an applicable provider.* The beneficiary must be under the care of an applicable provider, as defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant.

(b) *Under a physician plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 414.1515.

§ 414.1515 Plan of care requirements.

(a) *Contents.* The plan of care must contain those items listed in § 486.520(b) of this chapter that specify the standards relating to a plan of care that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program.

(b) *Physician's orders.* The physician's orders for services in the plan of care must specify at what frequency the services will be furnished, as well as the discipline that will furnish the ordered professional services. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished.

(c) *Plan of care signature requirements.* The plan of care must be signed and dated by the ordering physician prior to submitting a claim for payment. The ordering physician must sign and date the plan of care upon any changes to the plan of care.

Payment System

§ 414.1550 Basis of payment.

(a) *General rule.* For home infusion therapy services furnished on or after January 1, 2021, Medicare payment is made on the basis of 80 percent of the lesser of the following:

(1) The actual charge for the item.

(2) The fee schedule amount for the item, as determined in accordance with the provisions of this section.

(b) *Unit of single payment.* A unit of single payment is made for items and services furnished by a qualified home infusion therapy supplier per payment category for each infusion drug administration calendar day, as defined at § 486.505 of this chapter.

(c) *Initial establishment of the payment amounts.* In calculating the initial single payment amounts for CY 2021, CMS determined such amounts using the equivalent to 5 hours of infusion services in a physician's office as determined by codes and units of such codes under the annual fee schedule issued under section 1848 of the Act as follows:

(1) *Category 1.* Includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; chelation drugs; and other intravenous drugs as added to the durable medical equipment local coverage determination (DME LCD) for external infusion pumps. Payment equals 1 unit of 96365 plus 4 units of 96366.

(2) *Category 2.* Includes certain subcutaneous infusion drugs for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment equals 1 unit of 96369 plus 4 units of 96370.

(3) *Category 3.* (i) Includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(ii) Payment equals 1 unit of 96413 plus 4 units of 96415.

(4) *Initial visit.* (i) For each of the three categories listed in paragraphs (c)(1) through (3) of this section, the payment amounts are set higher for the first visit by the qualified home infusion therapy supplier to initiate the furnishing of home infusion therapy services in the patient's home and lower for subsequent visits in the patient's home. The difference in payment amounts is a percentage based on the relative payment for a new patient rate over an existing patient rate using the annual physician fee schedule evaluation and management payment amounts for a given year and calculated in a budget neutral manner.

(ii) The first visit payment amount is subject to the following requirements if a patient has previously received home infusion therapy services:

(A) The previous home infusion therapy services claim must include a patient status code to indicate a discharge.

(B) If a patient has a previous claim for HIT services, the first visit home infusion therapy services claim subsequent to the previous claim must show a gap of more than 60 days between the last home infusion therapy services claim and must indicate a discharge in the previous period before a HIT supplier may submit a home infusion therapy services claim for the first visit payment amount.

(d) *Required payment adjustments.* The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services and is subject to the following adjustments:

(1) An adjustment for a geographic wage index and other costs that may vary by region, using an appropriate wage index based on the site of service of the beneficiary.

(2) Beginning in 2022, an annual increase in the single payment amounts from the prior year by the percentage increase in the Consumer Price Index (CPI) for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(3)(i) An annual reduction in the percentage increase described in paragraph (c)(2) of this section by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(ii) The application of the paragraph (c)(3)(i) of this section may result in both of the following:

(A) A percentage being less than zero for a year.

(B) Payment being less than the payment rates for the preceding year.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Plan of care requirements.

(3) Medical necessity determinations.

PART 484—HOME HEALTH SERVICES

■ 6. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh unless otherwise indicated.

■ 7. Section 484.202 is amended by adding the definitions of ''HHCAHPS'' and ''HH QRP'' in alphabetical order to read as follows:

§ 484.202 Definitions.

* * * * *

HHCAHPS stands for Home Health Care Consumer Assessment of Healthcare Providers and Systems.

HH QRP stands for Home Health Quality Reporting Program.

* * * * *

■ 8. Section 484.205 is amended by—

■ a. Revising paragraph (g)(2)(i);

■ b. Removing paragraph (g)(2)(ii);

■ c. Redesignating paragraph (g)(2)(iii) as paragraph (g)(2)(ii);

■ d. Revising newly resdesignated paragraph (g)(2)(ii);

■ e. Adding paragraph (g)(3);

■ f. Revising the heading for paragraph (h); and

■ g. Adding paragraph (i).

The revisions and additions read as follows:

§ 484.205 Basis of payment.

* * * * *

(g) * * *

(2) * * *

(i) *HHAs certified for participation in Medicare on or before December 31, 2018.* (A) The initial payment for all 30-day periods is paid to an HHA at 20 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for all 30-day periods is paid at 80 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) *HHAs certified for participation in Medicare 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.

(3) *Payments for periods beginning on or after January 1, 2021.* HHAs receive a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP) prior to January 1, 2021.* * * *

(i) *Submission of Notice of Admission (NOA)*—(1) *For periods of care on and after January 1, 2021.* For periods of care beginning on and after January 1, 2021, all HHAs must submit a Notice of Admission (NOA) when either of the following conditions are met:

(i)(A) The plan of care has been signed by the certifying physician.

(B) If the physician-signed plan of care is not available at the time of submission of the NOA, then the submission must be based on either of the following:

(*1*) A physician's verbal order that—

(*i*) Is recorded in the plan of care;

(*ii*) Includes a description of the patient's condition and the services to be provided by the home health agency;

(*iii*) Includes an attestation (relating to the physician's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in § 484.115) responsible for furnishing or supervising the ordered service in the plan of care; and

(*iv*) Is copied into the plan of care and the plan of care is immediately submitted to the physician.

(*2*) A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.

(ii) [Reserved]

(2) *Consequences of failure to submit a timely Notice of Admission.* When a home health agency does not file the required NOA for its Medicare patients within 5 calendar days after the start of care—

(i) Medicare does not pay for those days of home health services from the start date to the date of filing of the notice of admission;

(ii) The wage-adjusted 30-day period payment amount is reduced by 1/30th for each day from the home health start of care date until the date the HHA submits the NOA;

(iii) No LUPA payments are made that fall within the late NOA period;

(iv) The payment reduction cannot exceed the total payment of the claim.

(v)(A) The non-covered days are a provider liability; and

(B) The provider must not bill the beneficiary for the noncovered days.

(3) *Exception to the consequences for filing the NOA late.* (i) CMS may waive the consequences of failure to submit a timely-filed NOA specified in paragraph (i)(2) of this section.

(ii) CMS determines if a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence specified in paragraph (i)(2) of this section.

(iii) A home health agency must fully document and furnish any requested documentation to CMS for a determination of exception. An exceptional circumstance may be due to, but is not limited to the following:

(A) Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.

(B) A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.

(C) A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.

(D) Other situations determined by CMS to be beyond the control of the home health agency.

§ 484.225 [Amended]

■ 9. Section 484.225 is amended by—

■ a. Removing paragraph (b).

■ b. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c).

■ c. In newly redesignated paragraph (c), removing the phrase ''paragraphs (a) through (c) of this section'' and adding in its place the phrase ''paragraphs (a) and (b) of this section''.

■ 10. Add § 484.245 to read as follows:

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

(a) *Participation.* Beginning January 1, 2007, an HHA must report Home Health Quality Reporting Program (HH QRP) data in accordance with the requirements of this section.

(b) *Data submission.* (1) Except as provided in paragraph (d) of this section, and for a program year, a HHA must submit all of the following to CMS:

(i) Data on measures specified under sections 1899B(c)(1) and 1899B(d)(1) of the Act.

(ii) Standardized patient assessment data required under section 1899B(b)(1) of the Act.

(iii) Quality data required under section 1895(b)(3)(B)(v)(II) of the Act, including HHCAHPS survey data. For purposes of HHCAHPS survey data submission, the following additional requirements apply:

(A) *Patient count.* An HHA that has less than 60 eligible unique HHCAHPS patients must annually submit their total HHCAHPS patient count to CMS to be exempt from the HHCAHPS reporting requirements for a calendar year.

(B) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf.

(C) *CMS approval.* CMS approves an HHCAHPS survey vendor if the applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years.

(*1*) For HHCAHPS, a ''survey of individuals'' is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes.

(*2*) All applicants that meet these requirements will be approved by CMS.

(D) *Disapproval by CMS.* No organization, firm, or business that owns, operates, or provides staffing for a HHA is permitted to administer its own HHCAHPS survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations will not be approved by CMS as HHCAHPS survey vendors.

(E) *Compliance with oversight activities.* Approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities, including allowing CMS and its HHCAHPS program team to perform site visits at the vendors' company locations.

(2) The data submitted under paragraphs (b)(1)(i) through (iii) of this section must be submitted in the form and manner, and at a time, specified by CMS.

(c) *Exceptions and extension requirements.* (1) A HHA may request and CMS may grant exceptions or extensions to the reporting requirements under paragraph (b) of this section for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) A HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS Home Health Annual Payment Update (HHAPU) reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) HHA CMS Certification Number (CCN).

(ii) HHAs Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) HHA's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under paragraph (b) of this section and a justification for the proposed date.

(3) Except as provided in paragraph (c)(4) of this section, CMS does not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (c).

(4) CMS may grant exceptions or extensions to HHAs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance, such as an act of nature, affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affects the ability of a HHA to submit data under paragraph (b) of this section.

(d) *Reconsiderations.* (1)(i) HHAs that do not meet the quality reporting requirements under this section for a program year will receive a letter of noncompliance via the United States Postal Service and notification in the Certification and Survey Provider Enhanced Report (CASPER) system.

(ii) An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at *HHAPureConsiderations@cms.hhs.gov* containing all of the following information:

(i) HHA CCN.

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, title, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider a reconsideration request unless the HHA has complied fully with the submission requirements in paragraph (d)(2) of this section.

(4) CMS will make a decision on the request for reconsideration and provide notice of the decision to the HHA through CASPER and via letter sent via the United States Postal Service.

(e) *Appeals.* An HHA that is dissatisfied with CMS' decision on a request for reconsideration submitted under paragraph (d) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

■ 11. Section 484.250 is revised to read as follows:

§ 484.250 OASIS data.

An HHA must submit to CMS the 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.

■ 12. Section 484.315 is amended by revising the section heading and adding paragraph (d) to read as follows:

§ 484.315 Data reporting for measures and evaluation and the public reporting of model data under the Home Health Value-Based Purchasing (HHVBP) Model.

* * * * *

(d) For performance year 5, CMS publicly reports the following for each competing home health agency on the CMS website:

(1) The Total Performance Score.

(2) The percentile ranking of the Total Performance Score.

Dated: June 14, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 20, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–14913 Filed 7–11–19; 4:15 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 482, 483, et al.
Medicare and Medicaid Programs; Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements; Final Rule
Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS–3342–F]

RIN 0938–AT18

Medicare and Medicaid Programs; Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the requirements that Long-Term Care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. Specifically, we are repealing the prohibition on the use of pre-dispute, binding arbitration agreements. We are also strengthening the transparency of arbitration agreements and arbitration in LTC facilities. This final rule supports residents' rights to make informed choices about important aspects of their health care.

DATES: These regulations are effective on September 16, 2019.

FOR FURTHER INFORMATION CONTACT: LTC Regulations Team: Diane Corning and Sheila Blackstock at (410) 786–6633.

SUPPLEMENTARY INFORMATION:

I. Background

Prior to October 2016, the requirements for Long-Term Care (LTC) facilities to participate in the Medicare and Medicaid programs, found in 42 CFR part 483, contained no provisions specific to the use of pre-dispute, binding arbitration agreements between LTC facilities and their residents. Then, on October 4, 2016, we published in the **Federal Register** a final rule entitled ''Reform of Requirements for Long-Term Care Facilities'' (81 FR 68688) (2016 final rule), that, among other revisions, established several requirements regarding the use of binding arbitration agreements by long-term care facilities.

Specifically, the 2016 final rule amended 42 CFR 483.70(n) to prohibit LTC facilities from entering into pre-dispute, binding arbitration agreements with any resident or his or her representative, or requiring that a resident sign an arbitration agreement as a condition of admission to the LTC facility. It also required that an agreement for post-dispute binding arbitration be entered into by the resident voluntarily, that the parties agree on the selection of a neutral arbitrator, and that the arbitral venue be convenient to both parties. The arbitration agreement could be signed by another individual only if allowed by the relevant state's law, if all of the other requirements in this section were met, and if that individual had no interest in the facility. In addition, a resident's right to continue to receive care at the facility post-dispute could not be contingent upon the resident or his or her representative signing an arbitration agreement. The arbitration agreement could not contain any language that prohibited or discouraged the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal and state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman. In addition, when a LTC facility and a resident resolved a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision was required to be retained by the facility for 5 years and be available for inspection upon request by the Centers for Medicare & Medicaid Services (CMS) or its designee.

On October 17, 2016, the American Health Care Association (AHCA) and a group of affiliated nursing homes filed a complaint in the United States District Court for the Northern District of Mississippi, Oxford Division seeking a preliminary and permanent injunction enjoining agency enforcement of the prohibition on pre-dispute, binding arbitration agreements, as provided in the regulation (§ 483.70(n)(1)) (AHCA litigation). On November 7, 2016, the district court preliminarily enjoined enforcement of that regulation prohibiting the use of pre-dispute, binding arbitration agreements (Civil Action No. 3:16–CV–00233).

As a result of the court's decision, on December 9, 2016, we issued a nation-wide instruction to State Survey Agency Directors, directing them not to enforce the 2016 final rule's prohibition of pre-dispute, binding arbitration provisions during the period that the court-ordered injunction remained in effect (S&C: 17–12–NH) *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-12.pdf*).

In addition, we determined that further analysis of the arbitration provisions was warranted. We re-evaluated the provisions to determine if a policy change would achieve a better balance between the advantages and disadvantages of pre-dispute, binding arbitration for residents and their providers and to ensure that the requirements complied with the terms of the January 30, 2107 Executive Order ''Reducing Regulation and Controlling Regulatory Costs'' (E.O. 13771). Based on this further analysis, we developed a revised regulatory approach to the use of arbitration agreements by Medicare and Medicaid participating LTC facilities.

On June 8, 2017, we published in the **Federal Register** a proposed rule entitled ''Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements'' (82 FR 26649) (2017 proposed rule). The 2017 proposed rule would remove the provision prohibiting pre-dispute, binding arbitration agreements and strengthen requirements regarding the transparency of arbitration agreements in LTC facilities. The proposal would support the resident's right to make informed choices about important aspects of his or her health care.

Statutory Authority

The agency has statutory authority to issue these rules under the authority granted by the Congress in the Nursing Home Reform Act, part of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), (Pub. L. 100–203, 101 Stat. 1330 (1987)). That statute added sections 1819 and 1919 to the Social Security Act (the Act), authorizing the agency to promulgate regulations that are ''adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys'' (Sections 1819(f)(1) and 1919(f)(1) of the Act). In addition, sections 1819(d)(4)(B) and 19199(d)(4)(B) of the Act authorizes the Secretary to impose ''such other requirements relating to the health and safety [and well-being [1]] of residents as [he] may find necessary''. This final rule does not purport to regulate the enforceability of any arbitration agreement, and, assuming that it limits the right of the Secretary to protect the rights of Medicaid beneficiaries, in our view, this rule does not pose any conflict with the language of the Federal Arbitration Act (FAA).

II. Provisions of the Proposed Regulations

In the 2017 proposed rule, we proposed to revise the provision related to pre-dispute, binding arbitration at § 483.70(n). We proposed to remove provisions that we believed on reconsideration did not strike the best balance between the advantages and

[1] Section 1819 only.

disadvantages of pre-dispute, binding arbitration. Specifically, we proposed to:

- Remove the requirement at § 483.70(n)(1) precluding facilities from entering into pre-dispute, binding agreements for binding arbitration with any resident or resident's representative;
- remove the provisions at § 483.70(n)(2)(ii) regarding the terms of arbitration agreements; and
- remove the prohibition at the root statement and § 483.70(n)(2)(iii) banning facilities from requiring that residents sign arbitration agreements as a condition of admission to, or as a requirement to continue to receive care at, a facility.

We proposed to retain provisions important to transparency of arbitration agreements. Specifically, we proposed to retain that:

- The agreement be explained to the resident and his or her representative in a form and manner that he or she understands, including in a language that the resident and his or her representative understands; and require that the resident acknowledge that he or she understands the agreement,
- the agreement must not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k), and
- when the facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee.

Finally, we proposed to add two transparency requirements. Specifically, we proposed to require that:

- The facility ensure that the agreement for binding arbitration is in plain language, and
- the facility must post a notice in plain language that describes its policy on the use of agreements for binding arbitration in an area that is visible to residents and visitors.

In response to the 2017 proposed rule, we received over 1,000 comments concerning the changes to the requirements regarding arbitration. Many comments were submitted by organizations that advocate for the rights of older adults, residents in nursing homes, or people with disabilities, including State Offices of the Long-Term Care Ombudsman.

III. Responses to Public Comments

We have reviewed all of the comments received and considered the concerns raised by all stakeholders. As a result, we have made some revisions to the proposed rule in response to public comments. Specifically, as discussed in detail below, we are finalizing our proposals to remove the requirement at § 483.70(n)(1) precluding facilities from entering into pre-dispute, binding agreements for binding arbitration with any resident or his or her representative, and the provisions at § 483.70(n)(2)(ii) regarding the terms of arbitration agreements. We are not finalizing the proposed removal of the provision at § 483.70(n)(2)(iii) banning facilities from requiring that residents sign arbitration agreements as a condition of admission to a facility. Therefore, facilities will continue to be prohibited from requiring any resident or his or her representative to sign an agreement for binding arbitration as a condition of admission to the facility. In addition, to address commenters' concerns that facilities may still coerce or intimidate the resident and his or her representative into signing the agreement, the facility must explicitly inform the resident or his or her representative that signing the agreement is not a condition of admission and ensure that this language is also in the agreement. We are finalizing provisions requiring that arbitration agreements be in a form and manner that the resident understands. However, we are not finalizing the proposed transparency related provisions that the facility must ensure that the agreement for binding arbitration is in ''plain language'' and that the facility post a notice regarding the use of agreements for binding arbitration in an area that is visible to residents and visitors. We are not finalizing the proposed removal of the provision specifying that a resident's right to continue to receive care at the facility must not be contingent upon signing an arbitration agreement. Finally, based on comments, we are adding a requirement that facilities grant to residents a 30 calendar day period during which they may rescind their agreement to an arbitration agreement. Our rationale for these changes, as well as our responses to comments we received on these issues is discussed below in detail.

A. General Comments

Comment: The overwhelming majority of commenters were opposed to our proposal to remove the prohibition on pre-dispute, binding arbitration agreements and recommended that we keep the requirements established by the October 2016 final rule. These commenters included consumer advocates, legal organizations, health care providers and practitioners, and members of the public. Some commenters believed that the current requirements contained long overdue improvements and the proposed rule was ''reversing course'' on those improvements. They agreed with the reasoning in the October 2016 final rule and often quoted the language in that rule. Some commenters favored the proposed revisions and supported finalizing the revisions as proposed. Others supported the proposed revisions but recommended specific changes. One commenter stated that they would support arbitration agreements, if they were properly structured. The commenter recommended requiring a rescission period, changes in the agreement terms, and even the creation of a governmental arbitration agency. Another commenter, a non-profit, long-term care provider, favored allowing voluntary, pre-dispute, binding arbitration agreements. Although the majority of commenters expressed support for the 2016 final rule, we also received comments from associations representing the LTC industry supporting the use of pre-dispute, binding arbitration agreements.

Response: In light of this broad spectrum of opinions, we have decided to revise § 486.70(n) by removing the prohibition on pre-dispute, binding arbitration agreements and creating protections against the abuses associated with arbitration agreements. Most significantly, arbitration agreements must not be used as a condition of admission to, or as a requirement for a resident to continue to receive care at, the facility. The agreement must explicitly grant residents the explicit right to rescind the agreement within 30 calendar days of signing it. The recommendation that there be the creation of a government arbitration agency is beyond the scope of this rule.

Comment: Some commenters stated that any regulations addressing arbitration are unnecessary. They stated that, under current law, residents, as well as all consumers, are already protected against fraud, unfairness, duress, and other types of overreaching in contracts by state contract and consumer protection law. For example, they contended that state laws already require the party seeking to enforce a contract, in this case the LTC facility

seeking to compel the resident or his or her representative to arbitrate a dispute, to demonstrate that the other party consented to the agreement. They asserted that a fundamental concept of contract law is a 'meeting of the minds' and 'a manifestation of mutual assent.' Thus, if the agreement is not in a language the resident understands or he or she does not understand the agreement for some other reason, it could be held invalid or unenforceable. Some commenters also pointed out that allowing LTC facilities to make signing an arbitration agreement a condition of admission might conflict with some states' laws. Another commenter pointed out that state courts would routinely invalidate unfair arbitration provisions on generally-applicable unconscionability principles for a variety of reasons, such as limitations on a consumer/resident's substantive rights to recover certain types of damages permitted to them by federal and state law, an unreasonably shortened statute of limitations, and unfair selection or excessive fees associated with selection of the arbitrator, arbitration venue, or access to an arbitral forum. Since residents can already challenge arbitration agreements in court under state law, these commenters believed residents' rights are already being protected and the arbitration requirements in the 2016 final rule are unnecessary. Some commenters even asserted that there should be no arbitration provisions in the LTC requirements because CMS has no expertise in this area and there is no evidence that state law is failing to adequately protect its citizens, including residents, regarding arbitration. Many commenters requested that, if we finalized our proposal to remove the prohibition on pre-dispute, binding arbitration agreements, CMS should remove all provisions discussing arbitration requirements. They stated that having no requirements regarding arbitration would be better for the residents than having any. Another commenter stated that, since much of the reimbursement received by these facilities is from the Medicare and Medicaid programs, which are funded by taxpayers, there should never be any limitations on the rights and remedies provided by state law.

Response: We agree with the commenters that many states' contract and consumer protection laws offer residents, as well as others, protections from unfair contracts, including pre-dispute, binding arbitration agreements that are unconscionable or are otherwise unenforceable under state contract law. This is why we revisited the protections promulgated in the October 2016 final rule. However, even though state law may provide some protection for residents, commenters raised a number of concerns that convinced us that these protections are limited and do not protect the unique needs of Medicare and Medicaid beneficiaries. Commenters pointed out that state laws differ and would likely offer varying levels of protection to residents. The requirements in this final rule offer consistent levels of protection to all residents in LTC facilities that are certified by the Medicare and Medicaid programs. Commenters also stated that many residents would find it difficult, if not impossible, to challenge these agreements in court. The resident or his or her family would generally have to retain an attorney. Since most residents' care is being paid for by either Medicare or Medicaid, some residents may not have the resources to pay an attorney. Many commenters also noted that engaging an attorney to challenge an arbitration agreement is also difficult because, should the challenge prove unsuccessful, the damages awarded through arbitration are generally lower than those awarded through judicial proceedings. If the award is smaller, the attorney's fee would likely also be smaller if the attorney took the case on a contingency basis. In addition, one commenter presented evidence of several instances indicating that challenging an arbitration agreement, even if successful, could result in years of delay before the claim could be resolved. The commenter cited 14 cases involving claims of abuse or neglect where the resident or their family successfully challenged the enforceability of an arbitration agreement. The commenter noted that it required between two and four years to resolve the issue of the enforceability of the binding arbitration before addressing the underlying abuse and neglect claim. Commenters said that some attorneys could determine that the delay associated with a particular case did not justify the resources and time needed to challenge the enforceability of a binding arbitration agreement. Some commenters were concerned that facilities could make it more difficult for residents to challenge arbitration agreements. Thus, some residents or their representatives would find it difficult, perhaps almost impossible, to retain an attorney to challenge the arbitration agreement in court. State law protections would be meaningless to residents if, as a practical manner, they did not have the ability to challenge these agreements in court. Thus, we believe that relying solely on state contract or consumer protection law, enforced primarily by private action, could in fact result in little to no real protections for the residents.

We believe the LTC requirements finalized in this rule are essential to ensure that arbitration agreements are not barriers to the resident receiving care and that there is no interference with federal, state, or local officials investigating quality of care issues. Therefore, in this final rule, we are retaining the existing requirement at § 483.70(n)(1), which prohibits the facility from using an arbitration agreement as a condition of admission. We are also retaining the requirement that an arbitration agreement cannot be used as a condition of admission to, or right to continue to receive care at, the facility. In addition, facilities must explicitly inform the resident or his or her representative that it is his or her right not to sign the agreement and this language must also be in the arbitration agreement. This provision will ensure that no resident or his or her representative will have to choose between signing an arbitration agreement and receiving care at the LTC facility. Although we are not finalizing a prohibition on pre-dispute, binding arbitration agreements, we believe that the requirements we are finalizing in this rule will provide the protections residents and their representatives will need to avoid being compelled to arbitrate disputes with LTC facilities without voluntarily and knowingly choosing to do so. The LTC facility must not require the resident or his or her representative sign an agreement for binding arbitration as a condition of admission to, or as a requirement for the resident to continue to receive care at, the facility. The facility must also ensure that the agreement is explained to the resident or his or her representative in a form and manner that he or she understands, and that individual(s) must acknowledge that he or she understands the agreement. The agreement must also explicitly grant the representative or his or her representative the right to rescind the agreement within 30 calendar days of signing it. This allows the resident to seek legal advice, if he or she chooses to do so. These requirements ensure that a decision on whether to sign the agreement is made only after the resident or his or her representative understands what he or she is agreeing to and that there is time to reconsider a decision to sign the agreement and seek legal advice, if he or she chooses

to do so. We believe that these protections address the concerns of the commenters who contended that LTC facilities were taking advantage of or coercing residents to sign these agreements.

We are also finalizing § 483.70(n)(2), which specifies that the agreement cannot contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman. This is the same requirement that was located at § 483.70(n)(2)(iv) in the 2016 final rule. Commenters informed us that a significant number of claims subjected to arbitration address quality of care issues. They also stated that it is quite often the case that the arbitral forum itself does not provide a way for the beneficiaries to seek full redress for their injuries. Commenters further stated that, when this happens, many substandard nursing homes continue providing poor care because the consequences for their conduct are insignificant. In light of these comments, we have concluded that the Secretary's statutorily-mandated duty to protect the health and safety of residents mandates that we create protections that assist LTC residents in knowingly and willingly entering into arbitration agreements that provide a neutral and fair arbitration process.

Comment: Several commenters were concerned about the effect that federal rules on arbitration might have on state laws addressing arbitration. They expressed particular concern that a federal regulation might be viewed as superseding state arbitration laws that are designed to protect residents and their families. State courts have invalidated arbitration agreements due to, among other reasons, unconscionability, fraud, and duress. Other state laws protect consumers from one-sided or cohesion contracts. The commenters claimed that these protections could not be overridden by the FAA because they apply to all consumer contracts and not arbitration agreements specifically. They expressed concern that a facility might argue that being in compliance with the current regulation would demonstrate that the arbitration agreement in question was not unconscionable. Other commenters believed that the arbitration requirements could conflict with the current consumer protection laws in some states and result in facilities avoiding or believing that those protections would no longer apply to residents, perhaps even those designed to prevent elder abuse. Some commenters were concerned that facilities would argue that their arbitration agreements were fair and that the court should compel arbitration because they complied with the arbitration requirements in the federal LTC requirements. This could make it more difficult for residents and their families to challenge an arbitration agreement in court. Other commenters also pointed out that, since it was against LTC facilities' interests to get residents or their families to sign arbitration agreements that could be struck down by a state court, they would not do so.

Response: We understand the commenters' concerns; however, we do not believe the requirements finalized in this rule will be detrimental to residents. These protections are in no way designed to supersede or interfere with state laws or other state contract and consumer protection laws. Many of these state laws provide for more protections than are set forth in the LTC requirements, and we believe it is in the best interests of the residents to have maximum protection afforded by law to protect their rights. This regulation is not intended in any way to preempt these state laws except to the extent any such laws are actually in conflict with this regulation. This regulation provides additional protections, and it is our hope that state court judges will understand this when deciding whether an arbitration agreement complies with any protections afforded residents under state law. In addition, the purpose of our LTC facility requirements are to protect the health, safety, welfare, and rights of residents. CMS establishes these minimum requirements that LTC facilities must meet to receive payment reimbursement from the Medicare and Medicaid programs. Hence, we do not believe that the arbitration requirements finalized in this rule would negatively impact any challenge to an arbitration agreement in state court.

Comment: Some commenters asserted that the confidential nature of arbitration could result in LTC facilities being able to hide, or avoid the consequences of, providing substandard or poor care. Commenters stated that since arbitration proceedings and the arbitrator's final decision are not matters of public record, that by allowing pre-dispute, binding arbitration agreements, LTC facilities could avoid some of the consequences of poor care, such as larger jury awards than those generally awarded in arbitration proceedings and a bad reputation that could dissuade potential residents from seeking admission to a facility.

Response: As discussed above, commenters have raised a variety of concerns about the confidential nature of arbitration. We share their concerns, and we are therefore finalizing the requirements mandating that LTC facilities retain copies of the signed arbitration agreement and the arbitrator's final decision for each dispute resolved through arbitration. They must retain these documents for 5 years after the resolution of the dispute, and make them available for inspection by CMS or its designee. This will allow us to gather data on how arbitration is being conducted in LTC facilities. We note the sincere concerns of many individual commenters that residents are not being treated fairly in facilities that use pre-dispute, binding arbitration agreements and that quality of care is negatively impacted by the use of these agreements. We believe that collecting these data would play a part in helping us determine the validity of these allegations on quality of care. For more information on our efforts to improve the quality of care in nursing homes, please see the Nursing Home Quality Initiative web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html.*

Comment: Some commenters agreed with our proposal to rescind the prohibition on pre-dispute, binding arbitration agreements. One organization stated that there was no policy justification for the prohibition or even regulating arbitration in any way because arbitration does not affect a resident's health, safety, or welfare. Another commenter disagreed with some of our statements in the 2016 final rule. This commenter noted that non-profit LTC providers are mission-driven and focus on providing the highest quality of care to their residents. The commenter noted that studies show that non-profit providers consistently provide the quality of care and service that exceeds that of for-profit LTC providers, because they do not have shareholders, investors, or owners that could pressure the facility to increase profits. The commenter also noted that there was no identified widespread deficiency in the care provided by non-profit LTC providers that would justify or be addressed by the prohibition of voluntary pre-dispute, binding arbitration agreements between the facility and its residents. The commenter stated the threat of excessive jury verdicts was unnecessary to provide incentive for non-profit

providers to either maintain or improve the quality of care they provide to their residents. A non-profit provider that served, and was set up to accommodate the Jewish community was concerned that a blanket prohibition on voluntary, pre-dispute, binding arbitration agreements would violate exercise of freedom of religion in violation of the Religious Freedom and Restoration Act. The commenter noted that under some interpretations of Talmudic law, disputes are not to be settled in secular courts. The commenter was concerned that if a resident either dies or another individual has authority to act for them, such other individual could file a lawsuit against the facility, and that such suit could conceivably be contrary to the deceased/incapacitated resident's beliefs. Essentially, they asserted that the relationship between the residents of their facility and the facility itself was not merely a commercial transaction since both the provider and the resident share mutual goals, aligned interests, and trust. However, they also stated that they did not object to common sense requirements that ensure that the agreement was voluntary. The commenter indicated that they would not object to requiring that the agreement be in plain language, explained to the resident in a form and manner he or she understands, and the resident must acknowledge that he or she understands the agreement.

Response: We appreciate that some data like the Nursing Home Data Compendium 2015 Edition (NHDC), indicate that non-profit LTC facilities tend to provide a better quality of care than some for-profit facilities, as evidence by fewer health deficiencies found on surveys. See *https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf*) (Accessed May 25, 2018). However, all ownership types of LTC facilities, including non-profits, have been cited for health deficiencies, sometimes very serious ones that result in a finding of actual harm or immediate jeopardy (NHDC, pp. 92–97). We agree with the commenters that completely prohibiting the use of pre-dispute, binding arbitration agreements could be too burdensome for some LTC facilities, regardless of whether they are non-profit or for-profit LTC facilities, because it would deny facilities a method of dispute resolution that can be faster and more economical than resolving the dispute in court. Thus, as we have noted previously, we are modifying the original rule to provide a balance between LTC facilities' desire for arbitration and the need for protections for LTC facility residents.

Regarding the commenter that was concerned that prohibiting a LTC facility from entering into pre-dispute, binding arbitration agreements with its residents could violate a resident's wishes, especially if they pass away or become incapacitated, we acknowledge that situation could happen. Since we have finalized the removal of that prohibition, we believe the commenter's concern has been addressed.

Comment: Some commenters stated that the proposed changes to the 2016 final rule were contrary to the evidence we presented and the comments we received when promulgating the 2016 rule. One commenter stated that the 2017 proposed rule did not address the evidence upon which we based the LTC facility requirements in the 2016 final rule. They asserted that the 2017 proposed rule was improper because it constituted a complete reversal of the policy in the 2016 final rule and, as such, CMS could not modify the 2016 rule without identifying or citing new evidence that justified the proposed changes. This commenter believed that the 2016 final rule presented an extensive literature review and an analysis of public comments that overwhelmingly demonstrated that pre-dispute, binding arbitration agreements should be prohibited. They insisted that the 2016 final rule constituted a carefully considered policy and should not be reversed on weak or non-existent evidence. Another commenter stated that, since the overwhelming number of comments opposed the use of pre-dispute, binding arbitration agreements because of the dangers they pose to the health, safety, and welfare of residents in LTC facilities, there is no reasonable basis for reversing the policy in 2016 final rule. The commenter stated that the 2016 final rule was clearly well justified by the evidence, the comments, and solid legal authority. They asserted that the modifications to the 2016 final rule contained in the 2017 proposed rule lacked the same level of support that underpinned the 2016 final rule. One commenter cited *Federal Communications Commission* v. *Fox Television Stations, Inc. (566 U.S. 502, 129 S.Ct. 1800 (2009))* (*FCC* vs. *Fox*), in which the U.S. Supreme Court addressed the legal standard governing whether an agency's reversal of a prior action is arbitrary and capricious. Based upon this opinion, the commenter stated that the critical protections in the 2016 final rule could not be rescinded without supplying a reasoned, record-based explanation for reversing its assessment of the evidence and comments that demonstrated the negative impact of forced arbitration on LTC residents.

Response: In the 2017 proposed and this final rule, we have provided a rationale for the requirements that are being finalized. As we noted earlier, the vast majority of commenters from the LTC industry have argued for the continued use of arbitration agreements for reasons of cost and efficiency. This regulation is designed to strike a balance between those concerns and protecting the needs of LTC residents. Furthermore, one court has preliminarily enjoined the agency from enforcing the prohibition against pre-dispute, binding arbitration agreements. Given our reconsideration of the available evidence and based on our review of the comments we received, as well as the comments received for the 2017 proposed rule, we believe the policies set forth in this final rule better balance the need for resident protections with the potential burden on LTC facilities' need for efficient and cost-effective operation. The court in *FCC* vs. *Fox* clearly indicated that an agency action would not be subject to heightened scrutiny simply because it changed its policy. It need only demonstrate that—(1) it is changing its position; (2) the new policy is permissible under the statute; (3) it has good reasons for the new policy and for the change of policy; and (4) that it believes the new policy is better. (*FCC* v. *Fox,* 566 U.S. 502, 515, 129 S.Ct. 1800, 1811.) We have explained our reasoning for the changes to the requirements and believe that these finalized requirements constitute a better policy. Concerning the ''evidence'' and comments referred to by the commenter, there was very little statistical data (although a great deal of anecdotal evidence and reportage) upon which we made our decisions that supported this provision of the 2016 final rule. Many comments were based upon anecdotal or personal experiences, and some commenters provided articles published in various general and legal periodicals. However, there was little solid social science research evidence to support these assertions. In light of the lack of statistical data, we believe the best way to strike a balance between the stakeholders supporting arbitration and residents having a complete understanding of the consequences of entering into an arbitration agreement is to issue regulations that ensure that these agreements not be used as a condition of admission to, or as a requirement for a resident to continue to

receive care at, the facility and the arbitration process is transparent to the resident and his or her representative. In addition, the requirement to retain copies of the arbitration agreement and the arbitrator's final decision will allow us to learn how arbitration is being used by LTC facilities and how this is affecting the residents.

Comment: Some commenters believed that the proposed changes to the arbitration requirements were politically motivated. Some believed that the motivation for these changes, which they believe benefit the providers at the detriment of the residents' rights, resulted from the change in administrations. One commenter noted the sudden and remarkable change between allowing pre-dispute, binding arbitration agreements in the 2017 proposed rule as compared to the 2016 final rule, which prohibited these agreements, despite CMS having earlier stated that ''there is significant evidence that pre-dispute arbitration agreements have a deleterious impact on the quality of care for [nursing home] patients'' in the 2016 final rule (81 FR 68791). One commenter even stated that they thought these changes would personally benefit some in the current administration.

Response: While there has been a change in Administration since the 2016 Final Rule was published, we disagree that change was the sole or primary reason for the proposed changes. As discussed above, at least one district court has rendered a decision that preliminarily enjoins us from enforcing the prohibition against pre-dispute, binding arbitration agreements. Following that ruling, we undertook a re-evaluation of the arbitration-related requirements in order to determine if a different approach would better serve both residents and facilities. That approach is reflected in this final rule, which includes some of the requirements in the 2016 Final Rule.

Comment: Some commenters that are opposed to pre-dispute, binding arbitration agreements asserted that post-dispute, binding arbitration agreements could be appropriate in a LTC setting. Since the agreement would be signed after the circumstances of the dispute had occurred, the resident could make an informed decision about settling the dispute with the facility through binding arbitration. However, other commenters were in favor of our proposal to remove the prohibition or ban on pre-dispute, binding arbitration agreements because they believed it was the equivalent of banning all arbitration. These commenters contended that parties often are unwilling to consider arbitration after a dispute arises. After a dispute arises, parties often have an emotional investment in resolving the dispute solely in their favor. This emotional investment often results in the parties not being able to evaluate the dispute logically or rationally. They may also believe that a willingness or offer to negotiate or submit the dispute to arbitration may appear as weakness. As a result, at least one of the parties would virtually always reject arbitration in favor of judicial proceedings, while another commenter asserted that pre-dispute, binding arbitration agreements were the most efficient way to ensure that parties do, in fact, arbitrate their disputes.

Response: As the comments make clear, there are strong arguments both for and against pre-dispute, binding arbitration agreements. This is a key reason why we are modifying this rule in an attempt to create a balance between both sides. As discussed above, we are finalizing our proposal to remove the prohibition on pre-dispute, binding arbitration agreements. Facilities and their residents will be able to enter into both pre-dispute and post-dispute binding arbitration agreements as long as facilities comply with the requirements that we are finalizing in this rule.

Comment: Some commenters were opposed to our proposal to remove the requirements at § 483.70(n)(2)(ii)(A), (B), and (C) in the 2016 Final Rule. Those requirements were that the agreement must: (A) Be entered into by the resident voluntarily, (B) Provide for the selection of a neutral arbitrator agreed upon by both parties, and (C) Provide for selection of a venue convenient to both parties. Commenters contended that these protections were critical for residents as they, at least partially, addressed the unequal bargaining power between the resident or his or her representative and the facility. Another commenter said that the selection of a neutral arbitrator was a key component of the LTC facility's accountability and consumer protection. One commenter pointed out that since residents have explicit rights to select their pharmacist and doctor, residents should also have a voice in the selection of the arbitrator and the location of the arbitration.

Response: We agree with the commenters. We believe these components are standard elements of arbitration and expect that these elements would be covered in the arbitration agreement. To ensure that the resident or his or her representative has the benefit of these components, this final rule retains the requirement that the facility provide for the selection of a neutral arbitrator agreed upon by both parties and provide for the selection of a venue convenient to both parties. However, we will remove the requirement that the resident or his or her representative sign the agreement voluntarily as we believe this provision is redundant. Other requirements in this section ensure that the agreement is explained and the resident or his or her representative knows that he or she does not have to sign the agreement as a condition of admission to, or as a requirement to continue to receive care at, the facility. In addition, we are finalizing a right for the resident or his or her representative to rescind the agreement within 30 calendar days of signing it. This provides the resident or his or her representative an opportunity to reconsider the agreement or, if they choose, seek legal advice. We believe that this right to rescind the agreement, as well as the requirements to provide for a neutral arbitrator agreed upon by both parties and the selection of a venue convenient to both parties, provide sufficient protection against an agreement that does not treat the resident fairly.

Comment: Some commenters appeared to interpret the district court's holding in the AHCA litigation as a ban on all arbitration agreements or other arbitration-specific requirements. Another commenter contended that the district court said that the forum for the dispute, whether resolved through judicial proceedings or arbitration, had no meaningful effect on the health, safety, and well-being of residents.

Response: We disagree with the commenter. As noted above, in our discussion of the relevant litigation, the only issue before the court was whether CMS could enforce § 483.70(n)(1)'s prohibition of pre-dispute, binding arbitration agreements. The court did not address issues beyond the arbitration prohibition.

Comment: Some commenters were against our proposal to remove the prohibition on pre-dispute, binding arbitration agreements because they believe the agreements are inherently unfair. They did not believe that any LTC facility requirements could overcome that inherent unfairness. They pointed to the imbalance of power between the resident and the facility, the facility having drafted the agreement with terms that would be favorable to the LTC facility, not the resident. In addition, staff rarely have the authority to re-negotiate the terms of the agreement with an individual prospective resident. Most residents and their representatives are likely unfamiliar with the implications of the

use of arbitration as a form of alternative dispute resolution and the consequences of signing the agreement. In addition, many commenters noted that residents would likely not seek legal advice before they sign the agreement. Other commenters contended that the inherent unfairness in using pre-dispute, binding arbitration agreements in LTC facilities is demonstrated by policy statements issued by various national legal and arbitration associations opposing the use of these agreements in health care disputes.

Response: We believe that the LTC requirements finalized in this rule will address the concerns identified by these commenters. We further acknowledge that various legal and arbitration associations have issued policy statements opposing the use of these agreements in health care disputes. In the 2016 final rule, we noted that three major legal or arbitration associations have made policy statements opposing continued use of pre-dispute, binding arbitration agreements (81 FR 68797). We believe these requirements address many of the concerns upon which those policy statements were based. As discussed below, the facility must not require the resident to sign one of these agreements as a condition of admission to, or as a requirement to continue to receive care at, the facility. The facility must also explicitly inform the resident or his or her representative that he or she is not required to sign the agreement as a condition of admission to or a requirement to continue to, or as a requirement to continue to receive care at, the facility; this language must be included in the agreement. This requirement will ensure that the resident or his or her representative is not placed into the position of deciding between signing an arbitration agreement or potentially the resident not receiving the care at the facility that he or she needs. The facility must ensure that the agreement is explained to the resident or his or her representative and he or she acknowledges that he or she understands the agreement. These requirements ensure that the facility has explained the agreement and should provide the resident or his or her representative with the opportunity to ask questions before he or she acknowledges that they understand the agreement. The agreement must also now explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it. This will provide the resident with the opportunity to reconsider the agreement and, if they chose, seek legal advice within that 30-day rescission period. The right to rescind must also be explained by the facility when it explains the rest of the agreement and the resident or his or her representative must acknowledge that he or she understands the right to rescind the agreement, as well as the remaining provisions in the agreement. We believe that the right to rescind the agreement within 30 calendar days of signing it addresses the commenters' concern that the requirements finalized in this rule are insufficient to protect residents' rights. We believe that the transparency requirements, the requirement that an arbitration agreement must not be used as a condition of admission, and that the facility must explicitly inform the resident or his or her representative of his or her right not to sign the agreement, will address the resident's ability to negotiate with the facility as well as provide residents, their representatives, and their families with the protections they need to ensure that they understand the agreement and can make a voluntary decision on whether to sign the agreement. They will further ensure that residents will not be forced to sign arbitration agreements to receive the care they need.

Comment: One commenter pointed out that in proposed § 483.70(n)(2)(i) the agreement had to be explained to the resident and his or her representative in a form and manner that he or she would understand, including a language that the resident or his or her representative would understand. However, in proposed § 483.70(n)(2)(ii), we stated that only the resident would have to acknowledge that he or she understands the agreement.

Response: We agree with the issue that the commenter pointed out. Section 483.70(n)(2)(ii) should also provide for the resident's representative to be able to acknowledge that he or she understands the agreements. Therefore, we have revised the language of that section to provide for the representative to acknowledge he or she understands the agreement.

B. Authority To Regulate Arbitration in LTC Facilities

Comment: Some commenters, particularly an association that represents LTC facilities, stated that the Secretary had no legal authority to regulate arbitration in any manner. They indicated that section 2 of the FAA provided that arbitration agreements are ''valid, irrevocable, and enforceable save upon such grounds as exist at law or equity for the revocation of any contract'' (9 U.S.C. 2). The last section of this clause, ''save upon such grounds as exist at law or equity for revocation of any contract'' is commonly referred to as the savings clause. The savings clause holds that arbitration agreements can be invalidated by generally applicable contract defenses, such as fraud, duress or unconscionability. Thus, the commenters stated that arbitration agreements or contracts should be treated as any other contract, and that the FAA's mandate could only be overcome by these generally applicable contract defenses. Some of these commenters also cited the district court's conclusion that the prohibition on pre-dispute, binding arbitration clauses was inconsistent with the requirement to treat arbitration contracts equally with all other contractual arrangements and that prohibition could not fit into the savings clause. Other commenters, however, strongly disagreed with the district court's decision in the AHCA litigation.

One commenter stated that the current LTC requirements already contain other limitations on the admissions contract. Specifically, the facility's contract cannot: (1) Request or require residents to waive their rights set forth in the federal regulations or in applicable state, federal or local licensing or certification laws; (2) request or require oral or written assurance that the resident is not eligible for, or will not apply for, Medicare or Medicaid benefits; (3) request or require residents to waive potential facility liability for losses of personal property; (4) request or require a third-party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility; and (5) charge, solicit, accept or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility (42 U.S.C. 1395i–3(c)(5), 1396r(c)(5), and 42 CFR 483.15(a)). The commenter stated that since federal law already targets multiple specific contract provisions for more stringent treatment, the 2017 proposed requirements actually provide special deference to arbitration agreements and as a result contradict and ignore the entire regulatory purpose and context of the LTC requirements. This commenter, in other words, claimed that since there are already restrictions on what can be in the admission contract, by removing the current restrictions on binding arbitration, we are actually giving

preferential treatment to arbitration agreements. In addition, the commenter appeared to be encouraging us to continue pursuing the AHCA litigation. Another commenter believed that the analysis contained in the 2016 final rule provided strong support for the Secretary to regulate arbitration agreements in LTC facilities.

All of these commenters stated there was Supreme Court precedent that the FAA mandate could only be overcome by a specific contrary congressional command. Since both the Medicare and Medicaid statutes are silent on arbitration, these individuals stated there was no contrary congressional command that gives the Secretary the authority to regulate arbitration. These commenters also stated that the district court properly rejected the arguments that the Secretary had authority based on her right to establish ''rights'' under the Medicare and Medicaid statutes and that she had authority to regulate these agreements, if the Secretary believed the regulation was necessary for the health, safety, and well-being of LTC residents.

Response: We recognize that the FAA is the overall federal statute addressing arbitration agreements. However, the FAA is concerned with general commercial contracts, whereas these rules arise under the Medicare and Medicaid statutes. The Medicare and Medicaid statutes explicitly grant the Secretary authority to ensure the protection of Medicare and Medicaid beneficiaries. Thus, this rule addresses a set of concerns that are unrelated to the reasons behind the FAA, as well as the statutory provisions contained within the FAA. Thus, while this rule modifies the original provisions regarding pre-dispute, binding arbitration clauses, we remain mindful of the comments claiming that these agreements potentially harm residents. We will, therefore, continue monitoring whether there is an effect on beneficiaries and, if we determine that the use of arbitration agreements poses a risk to the well-being of Medicare and Medicaid beneficiaries, we may revisit and revise the current policy. After reexamining the issue and reviewing public comments we received, at this point we believe that a balance can be struck that accommodates the use of arbitration agreements while also protecting the rights of LTC facility residents. Thus, we are finalizing the removal of the prohibition on pre-dispute, binding arbitration agreements and the provisions regarding the content of the agreement and implementing requirements we believe will provide greater transparency in the arbitration process.

Comment: Some commenters stated that CMS did not have the authority to change the arbitration requirements established by the 2016 final rule because removing or modifying the 2016 rule's prohibition of pre-dispute, binding arbitration agreements would harm residents' rights. These commenters pointed to the authorities contained in the Medicare and Medicaid statutes that the agency cited as authority for promulgating the 2016 Final Rule. Specifically, they agreed with the 2016 final rule's conclusions that the Medicare and Medicaid statutes provided the Secretary: (1) Authority to promulgate regulations that are adequate to protect the health, safety, welfare, and rights of resident and to promote the effective and efficient use of public moneys (42 U.S.C. 1395i–3(f)(1) 1396r(f)(1)); (2) Authority to establish such other requirements relating to the health and safety and well-being of residents as the Secretary may find necessary (42 U.S.C. 1395i–3(d)(4)(B), 1396r(d)(4)(B)); and (3) Authority to establish other rights(s) for residents, in addition to those set forth in statute to protect and promote the rights of each resident (42 U.S.C. 1395i–3(c)(1)(A)(xi), 1396r(c)(1)(A)(xi)) and the 2017 proposed rule (82 FR 26651) for a list of authorities). Based upon these authorities, these commenters stated that the Secretary lacked authority to remove requirements that would re-establish practices that are detrimental to residents, especially when one of the stated reasons for the changes is to reduce burden on providers. Another commenter added that the policy changes were contrary to the ''person-centered care'' framework established by federal law, policy, and regulation.

Response: While these commenters have reiterated concerns we raised in the 2016 final rule, other commenters have asserted that there are ways to protect the rights of residents without placing a complete prohibition on pre-dispute, binding arbitration agreements. The requirements we are finalizing in this rule are designed to accomplish the same goals as the 2016 rule, namely, protecting resident's rights in matters concerning the arbitration process. We believe the concept of ''person-centered care'', a crucial concept in the 2016 final rule, continues to be addressed in the requirements finalized in this rule. The facility must explain the agreement to the resident or his or her representative in a form and manner that the individual understands, and the individual must acknowledge that they understand the agreement. The agreement cannot be used as a condition of admission to, or as a requirement to continue to receive care at, the facility, so that the resident is not forced or coerced into signing the agreement to obtain, or continue to receive, the care that he or she needs. The facility must also explicitly inform the resident and his or her representative that they are not required to sign the agreement as a condition of admission and that this language in the agreement. The requirement that facilities retain copies of the signed agreements to binding arbitration and the arbitrators' final decisions will allow CMS to ensure that arbitration agreements are not used in a manner detrimental to quality of care concerns. We believe that these regulations will protect residents.

C. Impact on Health & Safety

Comment: Some commenters insisted that allowing LTC facilities to enter into pre-dispute, binding arbitration agreements would have a negative effect on residents because LTC facilities would be able to avoid some, or perhaps all, of the consequences of providing poor or inadequate care to their residents, including responsibility for illegal or even criminal acts. They stated that the threat of litigation was necessary to provide adequate incentive for the facilities to provide adequate care and a safe environment for the residents. When facilities use these agreements, their insurance premiums are lower since arbitration awards are usually lower than those received through judicial proceedings. Other commenters pointed out that there are also no public records of the arbitration proceedings. The public, including potential residents and their families, would likely not be aware of or even have the ability to learn of instances of poor care. Without the threat of lawsuits, some facilities might believe they are less accountable for the care they provide, which could result in substandard care and worse health outcomes for the residents. At best, binding arbitration would not provide sufficient incentive to improve resident care. One commenter stated that LTC facilities were already understaffed and the staff they do have are poorly trained. Since settling disputes through arbitration lowers the costs to the facilities, arbitration provides no incentive for facilities to increase the number of staff or improve their training. However, another commenter pointed out that the financial burden of LTC facilities being potentially subject to liability for damages determined by jury verdicts are spread out among the various nursing homes via standardized insurance premiums. Since the burden

associated with poor or substandard care is spread among all insured nursing homes, there is little incentive for any particular home to improve its care even if the facility is potentially exposed to the risk of jury-imposed damages. Another commenter pointed out that if LTC facilities provided appropriate care to their residents, they would not need to be so concerned with pre-dispute, binding arbitration agreements. Some commenters were also troubled about what they believed was an emphasis on eliminating unnecessary burden to providers over protecting LTC facility residents and ensuring that they receive proper care.

Response: While some commenters state that the existence of pre-dispute, binding arbitration agreements leads to a lower quality of care for residents, a significant number of other commenters have stated that there is, in fact, no link between arbitration and quality of care. At this point, all sides of the issue have credible arguments supporting their position. However, while both sides have good arguments, as noted earlier, there is little solid social science research evidence demonstrating that arbitration agreements necessarily have a negative effect on quality of care. As a result, we have determined that the best solution is to implement a regulation that accommodates arbitration while also protecting LTC facility residents from unfairly coerced agreements. We agree with the commenters that litigation and damage awards provide a way to hold LTC facilities accountable for substandard care. At the same time, however, it is not the only way to hold LTC facilities accountable for the quality of care they deliver.

We believe that these final regulations also hold facilities accountable in several additional ways. Specifically, we are finalizing the requirement that LTC facilities retain copies of the signed arbitration agreement and the arbitrator's final decision for each dispute resolved through arbitration for 5 years after resolution of that dispute. We also note that § 483.10(j) gives residents the right to voice grievances to the facility or any other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. These grievances could involve care and treatment received or not received, the behavior of staff or other residents, as well as any other concerns regarding the nursing home. LTC facilities must make prompt efforts to resolve the grievance. Section 483.12 requires, among other things, that residents be free from abuse, neglect, and exploitation. In accordance with section 1150B of the Act, 42 U.S.C. 1320b–25, any reasonable suspicion of a crime against a resident of an LTC facility must be reported to CMS and to one or more relevant law enforcement entities. All LTC facilities that are eligible to be paid through the Medicare and Medicaid programs must be certified and comply with our LTC facility requirements. One of those requirements, § 483.35, requires facilities to have sufficient nursing staff with the appropriate competencies and skill sets to provide nursing and related services to assure resident safety and attain or maintain the highest practical physical, mental, and psychosocial well-being of each resident. Specifically, we are finalizing the prohibition that facilities must not require any resident or his or her representative to enter into an agreement for binding arbitration as a condition of admission to the facility. We are also retaining the prohibition on facilities requiring a current resident or his or her representative to sign an agreement in order to continue to receive care at the facility. The facility must also explicitly inform the resident or his or her representative of these prohibitions and this language must be included in the agreement. This holds the facility accountable by ensuring that the facility cannot coerce or apply unreasonable pressure on a resident or his or her representative by implying the resident would not receive the care he or she needs without signing the agreement. We are also finalizing the requirements that the facility ensure that the agreement is explained to the resident and his or her representative, and that the resident or his or her representative acknowledge that he or she understands the agreement. This holds the facility accountable by ensuring that the agreement is explained to, and understood by, the resident or his or her representative before the agreement is signed. We are also finalizing the requirement that the agreement explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it. This holds the facility accountable by ensuring that the resident or his or her representative has the opportunity to reconsider his or her decision and seek legal advice, if they choose to do so. We are also finalizing the requirement that the agreement not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representative of the Office of the Long-Term Care Ombudsman. This requirement holds the facility accountable by ensuring that neither the resident nor anyone else could be intimidated or discouraged from discussing the circumstances around the dispute with surveyors or others responsible for evaluating the quality and safety of the resident's care and the facility's compliance with regulatory requirements. In addition, we are finalizing the requirement that LTC facilities retain copies of the signed arbitration agreement and the arbitrator's final decision for 5 years after any dispute is resolved through arbitration and make these documents available for inspection upon request by CMS or its designee. This holds LTC facilities accountable because it allows surveyors to review the issues raised in the arbitration and to determine if they raise concerns about the quality and safety of the resident's care and the facility's compliance with regulatory requirements. Surveyors can then incorporate problems identified through arbitration into the current survey in order to determine if the LTC facility has taken steps to prevent the problem from reoccurring. The LTC requirements are enforced through both routine and complaint surveys and certification process. We note that the survey and certification provisions set forth in sections 1819(g)(2)(A)(iii) and 1919(g)(2)(A)(iii) of the Act and in 42 CFR 488.308 require that each skilled nursing facility and nursing facility be subject to a standard survey no later than 15 months after the last day of the previous standard survey and that the statewide average interval between standard surveys of skilled nursing facilities and nursing facilities not exceed 12 months. As part of the standard Long Term Care Survey Process, surveyors ask for and review the facility's admission packet, which would include arbitration agreements presented to residents. If violations of these requirements are found, LTC facilities could face, among other things, being cited with deficiencies, being put on a correction plan, or even losing or not obtaining certification in the Medicare program. For more information on CMS' efforts to improve the quality of care in nursing homes, please see the Nursing Home Quality Initiative web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html.*

Comment: Some commenters agreed with our proposal to remove the

prohibition on pre-dispute, binding arbitration agreements. They claimed that the prohibition of these agreements would substantially increase the cost of resolving disputes which, in turn, would reduce the financial resources available for resident care. In addition to the increased costs of judicial litigation, these commenters claimed their insurance premiums will rise if disputes cannot be resolved through arbitration. This, too, they claim, would reduce the resources a provider could use for improving the quality of care. These commenters further asserted that rising insurance premiums would either cause some nursing homes to cease operations or bear an additional substantial financial burden. Since Medicare and Medicaid compensation rates are fixed, according to the commenter, nursing homes could be forced to make cuts that could affect resident care and would likely have to increase costs to those who are not on one of these government programs. This could make care unaffordable for families without improving the quality of care. Instead of being beneficial to residents, prohibiting pre-dispute, binding arbitration agreements could actually result in being detrimental to all residents, regardless of payor. However, other commenters pointed out that facilities also have a burden associated with using pre-dispute, binding arbitration agreements and that prohibiting them would reduce burden for the providers. Using pre-dispute, binding arbitration agreements for every resident is both a time-consuming and unnecessary process if the facility is providing appropriate care for its residents.

Response: While there is little empirical evidence supporting the consequences claimed by these commenters, we also agree that prohibiting pre-dispute, binding arbitration agreements could impose an unnecessary burden on LTC facilities. Prohibiting the use of these agreements would deny facilities a method of resolving disputes that is potentially more cost effective and efficient. We also agree with the commenters that stated that facilities have a burden associated with using pre-dispute, binding arbitration agreements due to the regulatory requirements with which the facilities must comply. Even before these requirements became effective, there was a burden associated with using these agreements, such as developing the agreement, speaking to and obtaining consent from residents or their representatives, and maintain copies of the agreements. However, since no facility is required to use these agreements, any burden associated with them is the facility's choice. However, we disagree with one commenter's contention that for facilities that are providing appropriate care the burden associated with pre-dispute, binding arbitration agreements is time-consuming or unnecessary. Even facilities that provide appropriate care could have disputes with their residents. Thus, these regulations allow the use of arbitration so long as LTC facilities comply with the requirements finalized in this rule.

Comment: One commenter supported our proposal to remove the prohibition on pre-dispute, binding arbitration agreements because they believe it disrespectful to seniors and their families' capability, dignity, and autonomy. State law presumes seniors are fully competent unless there is evidence to the contrary. They noted that mental deterioration only results from certain diseases, not aging alone. Constitutional and other legal rights cannot be taken away solely because of age and certainly not without due process. Yet, the prohibition on pre-dispute, binding arbitration agreements presumes that residents are not competent to make an informed and appropriate choice concerning an arbitration agreement. The commenter believed it is insulting and ignorant to suggest that every senior who enters into a pre-dispute, binding arbitration agreement is either coerced, uninformed, or has been taken advantage of by the facility. These same individuals are signing many different documents during the admissions process, including the contract with the LTC facility, and these are not being questioned. This prohibition essentially denies residents the legal right to enter into voluntary contracts due to the assumption of incompetence of the resident. The choice to sign one of these agreements can hardly be considered less reasonable or valid than the choices made by residents that are influenced by promises of a lawyer seeking to sue the nursing home. However, other commenters, including a national association of health care providers, stated that residents cannot make an informed decision concerning whether to sign a pre-dispute, binding arbitration agreement without knowledge of the circumstances surrounding the dispute, which can only be known after the dispute arises. Other commenters stated that during the admissions process, residents are not likely to contemplate the possible disputes that could arise later as a result of the actions or lack to action by the LTC facility's management or staff, including physical abuse and neglect, sexual assault, and even wrongful death of the resident. Further, residents are frequently admitted during a time of stress and often after a decline in their health or directly from the hospital and these circumstances make it extremely difficult for LTC residents or their representatives to make an informed decision about arbitration.

Response: The prohibition against pre-dispute, binding arbitration agreements was never intended to convey any disrespect to residents. However, we cannot ignore the comments we received from patient advocacy groups and other health care providers that raised a number of concerns about the way LTC residents are presented with arbitration agreements and the harm that results when residents unwittingly sign arbitration agreements that are later found to be against their best interests. Therefore, the intent was solely to address these concerns.

Comment: Numerous commenters opposed any regulation that does not prohibit facilities from requiring that a resident or his or her representative sign a pre-dispute, binding arbitration agreement as a condition of admission. They stated that no person in need of care should be put in the position of choosing between signing one of these agreements or not receiving care. Nursing home care is often sought during a time of crisis. The individual has usually suffered a serious injury, surgery, or some other condition that has resulted in a substantial decrease in their health or their ability to care for themselves. In most cases, the choice of nursing home is severely limited. All of these factors create stress for both the individuals who need care, their families, and other caregivers. Some commenters stated that it was unrealistic to presume that these individuals are in a position to fully understand the consequences of a pre-dispute, binding arbitration agreement. Other commenters noted that the number of LTC facilities practically available to an individual may be extremely limited. For example, it is entirely reasonable for a resident to want to remain close to family and friends. However, many times there is only one nursing home within a reasonable geographic distance of the resident's family or friends. Likewise, factors such as the type of payment the facility will accept, the health care and services it offers, and the availability of beds limit an individual's choice of facilities. Therefore, many residents may only have a few, and perhaps only one or two, suitable facilities from

which to choose. Once a facility is selected, commenters stated that some residents believe they have no choice but to sign the agreement in order to obtain the care they need.

Response: We agree with the commenters that a pre-dispute, binding arbitration agreement should not be a condition of admission. In the 2017 proposed rule, we proposed removing the prohibition set forth at § 483.70(n)(1) against using these agreements as a condition of admission because we did not believe that the prohibition struck the right balance between the advantages and disadvantages with pre-dispute, binding arbitration agreements. However, the overwhelming number of commenters who commented on this proposal were against allowing the facility to make signing a pre-dispute, binding arbitration agreement a condition of admission. We agree that many residents or their families usually do not have many LTC facilities to choose from and the existence of one of these agreements as a condition of admission is not likely to be a deciding factor in choosing a facility. We also agree that no one should have to choose between receiving care and signing an arbitration agreement. Therefore, we have finalized § 483.70(n)(1) to state that the facility must not require any resident or his or her representative to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility. In addition, the facility must inform the resident or his or her representative of these rights and ensure that this language is in the agreement.

Comment: Some commenters were concerned that allowing pre-dispute, binding arbitration agreements to be used as a condition of admission would encourage LTC facilities that do not use these agreements to begin using them. Another commenter questioned whether this could eviscerate one of the fundamental protections under the FAA and contract law, that a contract is not enforceable if it is entered into as a result of coercion, misrepresentation, fraud, duress, or otherwise was unconscionable. One commenter noted that state courts have often found that requiring the resident to sign one of these agreements as a condition of admission was unconscionable. Some commenters were concerned that LTC facilities would have less incentive to provide quality care or improve their care to their residents, or perhaps, even worse, view these agreements as ''get out of jail free cards.''

Response: We note that until the 2016 final rule was issued, there were no LTC facility requirements regarding arbitration. LTC facilities were allowed to use these agreements and still maintained that right until the effective date of that rule. This rule was never enforced due to litigation. This final rule would allow the use of arbitration agreements as long as LTC facilities comply with the requirements finalized in this rule. We believe that residents and their families will have their rights protected and that there will be transparency in the arbitration process under this final rule. We believe that concerns about a link between the use of arbitration agreements and quality of care can be alleviated by ensuring that surveyors have access to key documents relating to the arbitration, including arbitral decisions. By prohibiting secrecy, surveyors can review the facts giving rise to the arbitration and keep those issues in mind when conducting the survey to, among other things, determine whether the LTC facility has taken steps to prevent similar problems from arising. In order to avoid secrecy problems, under these regulations Medicare-participating LTC facilities must retain copies of the signed arbitration agreements and the arbitrator's final decision for each dispute settled through arbitration. In addition, as discussed below, the LTC facility requirements are enforced through a survey process, including both routine surveys and complaint surveys. When surveyors are investigating a complaint that refers to issues related to the arbitration agreements and/or arbiter's final decisions, surveyors will be directed to collect the relevant information (for example, the admissions packet, arbitration agreement, and record of arbitrator's hearing).

After finalization of the regulation, we will monitor trends of compliance and take any actions warranted based on these trends. Failure to comply with these requirements can result in sanctions, up to and including being de-certified from the Medicare program. Hence, these agreements are neither a ''get out of jail free card'' nor an incentive to provide substandard care or not improve the care they provide to their residents. Concerning the commenters' concerns that allowing these agreements to be used as a condition of admission would affect the fundamental concept that contracts must be entered into voluntarily and with consent, we share their concerns about individuals being coerced into signing one of these agreements, especially if they believe the resident will not receive the care he or she needs if the agreement is not signed. As discussed above, we have modified the proposed rule to resolve these concerns by precluding LTC facilities from requiring an arbitration agreement as a condition of admission to, or as a requirement to continue receiving care at, the facility. The facility must also inform the resident or his or her representative of these rights and ensure that this language is in the agreement.

Comment: Some commenters were concerned about current residents in LTC facilities being coerced into signing pre-dispute, binding arbitration agreements. These commenters pointed out that when current residents are approached with these agreements, even if signing the agreement is presented as voluntary, they might feel pressured to sign it for fear of not being allowed to stay at the facility.

Response: This final rule makes clear that a resident must be informed, and the arbitration agreement must state, that signing an arbitration agreement is not a condition of admission nor is it necessary to remain at the facility. In addition, the agreement must explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it. Thus, if a LTC facility complies with the rule, we believe residents should not feel that they have no choice in signing the arbitration agreement. In addition, a facility that transferred or discharged a resident for failure to sign an arbitration agreement (whether pre- or post-dispute) would risk termination from the Medicare and Medicaid programs. Under current regulations, residents cannot be transferred or discharged from a LTC facility due to their decision not to sign an arbitration agreement. Section 483.15(c), formerly § 483.12(a)(2), ''Transfer and discharge'', sets forth the permissible reasons a LTC facility can transfer or discharge a resident. For a current resident, the permissible reasons a facility may transfer or discharge a resident are: (1) It is necessary for the resident's welfare and the resident's needs cannot be met in their facility; (2) the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; (3) the safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident; (4) the health of individuals in the facility would otherwise be endangered; (5) the resident failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility; and, (6) the facility ceases to operate. Failure to sign an agreement for binding

arbitration is not a permissible reason. If a LTC facility attempted to transfer or discharge a resident after either the resident or his or her representative refused to sign the agreement, they could be in violation of § 483.15(c) and CMS could take action, including citing the facility for a deficiency. Thus, we believe that residents are still protected from being transferred or discharged because of a refusal to sign an arbitration agreement. *See Binding Arbitration in Nursing Homes, Survey and Certification Letter dated January 9, 2003* (S&C–03–10) (available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCletter03-10.pdf*).

Regarding current residents that have already signed arbitration agreements, we note that CMS does not have the power to annul valid contracts. Current arbitration agreements that are valid under the applicable state or other relevant jurisdiction's laws are still valid. We do believe that it would be good policy and we would encourage LTC facilities to offer current residents who have signed arbitration agreements the opportunity to rescind those agreements and proceed with a new agreement that conforms to these regulations. However, these provisions are only effective prospectively.

Comment: Many commenters contended that claims for abuse, neglect, and malpractice are not appropriate for arbitral resolution. Other commenters noted the types of claims commonly brought against LTC facilities such as pressure ulcers, broken bones, malnutrition, dehydration, asphyxiation (due to improper restraints), sexual assault and other criminal activities are also inappropriate matters for arbitration.

Response: From these comments, it is our understanding that the commenters believe that claims related to possible medical negligence or malpractice or claims that involved serious physical or emotional injury need to be resolved in a public forum where the circumstances surrounding the claim would result in a public record. They apparently believe that settling a dispute through judicial proceedings has a more important and positive effect on improving the quality of care for residents and holding the LTC facility responsible for poor care than if the dispute had been settled through arbitration. Certain claims, especially those related to a serious injury to a resident's physical and/or his or her emotional well-being, are especially disturbing. We understand that many individuals would prefer that these types of claims be treated differently. However, we believe that either type of forum, arbitration or judicial proceedings, can be an appropriate forum to resolve disputes. We also believe that a fundamental requirement for arbitration would be that the arbitral forum has the expertise to handle the dispute presented by the parties. Thus, we do not believe it is appropriate to prohibit certain types of claims from being resolved in arbitration. This could lead to confusion and some grievances or concerns not being addressed appropriately. Some claims may not fit into a single, clearly designated category, such as when there are features of the dispute that could be put it into multiple categories. Resolving the dispute could result in some portions of the dispute being resolved through arbitration but others having to go into judicial proceedings. Some matters may also involve CMS enforcement surveys or audits. We would also note that notwithstanding the existence of an arbitration agreement, the LTC facility is obligated to comply with all requirements for participation. Specifically, there are requirements in our regulations for reporting abuse, neglect, misappropriation, and maltreatment (See § 483.12 Freedom from abuse, neglect and exploitation). The resolution of any dispute through arbitration or judicial proceedings would not interfere with the facility's responsibility to report abuse or negate our ability to take appropriate enforcement action. The relevant law enforcement entities could also take appropriate action against individuals. In addition, § 483.70(n)(5) of this final rule provides that the agreement may not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman. This provision ensures that residents also have the right to speak to officials about any concerns they have regarding their treatment. Finally, the recordkeeping requirements finalized in this rule will also allow us to learn how these types of claims are being treated and resolved through arbitration in LTC facilities.

Comment: Despite the oversight that results from surveys, ombudsmen, and other mechanisms, some commenters believed these are insufficient to protect residents from neglect, abuse, or other harm. One commenter, who had been a therapist and is now a LTC ombudsman, indicated that abuse and disregard of residents' rights was widespread in LTC facilities. The commenter also indicated that when violations were identified and reported to his or her state's Department of Health, it was rare for a facility to be held accountable for its actions. Other commenters also noted that they saw or their loved ones had experienced abuse and/or neglect. Some commenters drew our attention to media reports about incidents of abuse, neglect, and even criminal offenses against in LTC facilities. Some commenters pointed to a recent CNN investigation on LTC facilities (aired on March 17, 2017) as evidence of the poor and negligent care residents were enduring in these facilities, available at *http://www.cnn.com/2017/03/17/health/nursing-home-sex-abuse/index.html.* That investigation found that more than 1,000 nursing homes have been cited for mishandling alleged cases of sexual abuse. Another commenter cited other articles that also indicated that elder abuse and elder abuse in nursing homes was a serious problem.

Response: Given the lack of hard social science data, we do not believe that removing the ban on pre-dispute, binding arbitration agreements will increase the occurrence of any of the serious incidents that the commenters and the media are describing. We believe that the requirements finalized in this rule, as well as the other LTC facility requirements, will work together to reduce, and hopefully, eliminate such incidents. For example, in this final rule the results of disputes settled through arbitration will no longer be private but subject to inspection by CMS or its designee (§ 483.70(n)(5)). Other current requirements, including the requirements to report instances of abuse, neglect, exploitation, and mistreatment as set forth in § 483.12(c), will also address these instances to ensure that facilities are reporting to the state and other appropriate entities. In addition, we will continue to monitor the care residents receive through our routine and complaint survey processes. Information on the Quality, Certification and Oversight Reports are available at: *https://qcor.cms.gov/main.jsp.* Nursing Home Compare data sets are available at: *https://data.medicare.gov/data/nursing-home-compare.*

D. Transparency

Comment: Regarding the proposal to retain the requirement that would bar any arbitration agreement from including any language that would prohibit or discourage a resident or anyone else from communicating with

federal, state, or local officials, one commenter noted that they were unaware of any resident being precluded from discussing any quality-of-care concerns with any government official. In addition, the inclusion of such a provision in the agreement could invalidate the agreement, or at least that provision, as being unconscionable. No arbitration agreement could limit the power of government regulators from taking action when there is a complaint. They also point out that there are ample protections for residents to communicate with government officials. For example, facilities must not prohibit or discourage residents from communicating with federal, state, or local officials; facilities must provide residents with written notice of how they can file a complaint with the State Survey Agency and information and contact information for filing grievances of any suspected violation of state or federal nursing facility regulations; and facilities must post information regarding the filing of complaints with the State Survey Agency in a form and a manner accessible and understandable to residents and their representatives (§ 483.10(k), (g)(4)(i)(D), (vi), and (g)(5), respectively). There is no justification for an arbitration-specific provision and its inclusion in the requirements. It demonstrates a suspicion about arbitration which is inconsistent with the federal policy embodied within the FAA and the proposed changes.

Response: We disagree with the commenters. We believe that there does need to be an arbitration-specific requirement to ensure that there is no language in the LTC facility's arbitration agreement that could be interpreted as either discouraging or prohibiting not only the resident but anyone else from communicating with federal, state, or local officials. Comments we received contained anecdotal evidence of so-called 'gag-clauses' being common in arbitration agreements and that residents and family members were uncertain if they could talk to surveyors about a quality concern that was arbitrated. The requirements cited by the commenters only apply to residents, no one else. Since others in the LTC facility, including staff and other residents and visitors, may have important information surrounding the circumstances of a dispute between a resident and the LTC facility, it is important that the facility not be able to prevent or discourage anyone, such as family, friends, volunteers, other residents or staff, from communicating with any government officials, especially surveyors that need to investigate the care being provided to residents. In addition, if an arbitration agreement contained such language, we believe that it is quite likely that the resident could interpret it as overriding the protections cited by the commenter, or at least result in confusion. Concerning the commenter's contention that, if a dispute arises, the resident has the opportunity to challenge the existence of the agreement, we do not believe that is sufficient. To vacate an award or decision procured through arbitration, courts are limited to certain causes, if proved. These limitations are set forth in 9 U.S.C. 10a and include, but are not limited to, the award was procured through corruption, fraud, or undue means; evident partiality or corruption in arbitrators, and misconduct by arbitrators such that the rights of any party were prejudiced. Among other things, this regulation ensures that arbitral decisions be available for surveyors. As we have explained, we have concluded that it is important for surveyors to be able to review these documents to determine compliance with requirements. Thus, this arbitration-specific requirement will ensure that the resident is not misled or confused about his or her right to communicate with federal, state, and local officials about the circumstances surrounding the dispute.

Comment: One commenter was concerned about the recordkeeping requirements mandating that a signed copy of the agreement and decision must be retained by the LTC facility for 5 years and be made available for inspection by CMS. They believe that this unjustifiably singles out arbitration and is unduly burdensome. They also noted that CMS had not provided any reason for the facility to retain the arbitration agreement for the 5 years after the dispute was resolved. If a dispute arises, the resident has the opportunity to challenge the existence of the agreement. The commenter stated that there was no reason to add this additional recordkeeping burden on facilities, and no justification for singling out arbitration agreements for this requirement. For example, CMS has not proposed that all settlement agreements be retained for 5 years.

Response: Unlike court decisions and settlement agreements, there are no public records when a dispute is settled through arbitration. These recordkeeping requirements are intended to ensure that CMS can fully evaluate quality of care complaints that are addressed in arbitration and assess the overall impact of these agreements on the safety and quality of care provided in LTC facilities. Many commenters were concerned that these agreements have a negative effect on the care residents receive in these facilities. Some commenters, as noted previously, stated that pre-dispute, binding arbitration agreements would lead to a declining standard of care for residents. The requirement for facilities to retain these documents for CMS or its designee to review will assist CMS in determining to what extent quality of care issues are addressed in arbitration and in ensuring that quality of care concerns that are the subject of arbitration can be thoroughly investigated, if needed, in specific cases, or in aggregate.

Comment: Some commenters were dissatisfied with the transparency requirements we proposed. They believed that these requirements offered little, if any, value. The imbalance of power between the resident and the facility, as well as the stress a resident may experience during the admissions process, could exert pressure on the resident to sign a pre-dispute, binding arbitration agreement, even if the facility does not intend to pressure the resident. One commenter stated that the transparency provisions simply do not protect residents from the coercive nature of the process. We believe that the commenter is referring to the unequal bargaining power between the resident and the facility, especially concerning knowledge of and control of the arbitration process and resident's need for care. Other commenters stated that it was unlikely that a resident would delay signing the admissions contract in order to seek legal advice, since the predominant concern will be obtaining the care the resident needs. Two commenters discussed a cooling off or rescission period. One commenter, an organization that supports the overall health and well-being of seniors, children, and those with special needs, made some specific recommendations concerning the use of pre-dispute, binding arbitration agreements. One of those recommendations is that the agreement should include a rescission period. This would give residents and their representatives a chance to thoroughly read the agreement and reconsider whether they should agree to its terms. They would also have time to seek legal advice, if they chose to do so. If they change their minds regarding the agreement, they would then have time to rescind it. The other commenter, a major organization that represents nursing homes, noted that its own model agreement for arbitration agreements contained a provision for a 30-day rescission period. That

commenter noted that many nursing homes already include safeguards in their contracting process, including a provision for a 30-day rescission process, so that a resident and his or her representative has a meaningful opportunity to reconsider whether he or she wants to settle any disputes with the LTC facility through arbitration. Therefore, we are adding a requirement that the agreement must allow the resident or his or her representative to rescind the agreement within 30 calendar days of signing it at § 483.70(n)(3).

Response: We acknowledge that, despite the requirements in this rule that would prohibit a LTC facility to have a resident sign an arbitration agreement as a condition of admission, some residents or their representatives might feel pressure to sign these agreements. We agree with the commenter who suggested that a rescission period would provide residents time to get beyond the admissions process and consider whether they want to be bound by the arbitration agreement. It will also give them time to obtain legal advice, if they chose to do so. Therefore, we are adding a requirement that the agreement must allow the resident or his or her representative to rescind the agreement within 30 calendar days of signing it at § 483.70(n)(3).

Comment: Some commenters stated that the transparency provisions do not overcome the fundamental problem with pre-dispute, binding arbitration agreements, which is the lack of an informed agreement. The decision to sign a binding arbitration agreement can never be informed unless both parties are fully aware of the circumstances surrounding the dispute and the consequences of agreeing to settle the dispute through arbitration. This can only happen after the circumstances that resulted in the dispute have already occurred.

Response: We agree that, when a pre-dispute, binding arbitration agreement is signed neither the resident nor the LTC facility are aware of the circumstances surrounding any future dispute between them. However, by signing one of these agreements, the parties are not settling a dispute but deciding the forum in which any future disputes would be settled. We believe that the requirements finalized in this rule provide the transparency necessary for residents to understand the ramifications of signing an arbitration agreement.

Comment: Some commenters believed that posting a notice was not only unhelpful but also confusing. One commenter noted that so many items must already be posted that any notice on arbitration would likely not stand out.

Response: We agree with the commenters. Posting a notice would not likely serve any purpose other than to require more paperwork. Thus, we are not finalizing the requirement that LTC facilities post a notice concerning their policy on arbitration agreements.

Comment: We received mixed comments on the fairness of arbitral forums. Some commenters expressed concerns that in some situations arbitrators had awarded the resident or his or her family much less compensation then would have been expected if the dispute had been resolved through a formal judicial proceeding or had found that the LTC facility was not responsible for an injury to a resident when it was likely that a judge or jury would have. Some commenters pointed to specific instances of residents or their families receiving little to no compensation. Other commenters stated that residents and their families did as well or better with disputes settled through arbitration than they would have through formal judicial proceedings. Other commenters stated that residents, especially those that are in facilities for an extended length of time, are vulnerable. As discussed above, about half of LTC facility residents have been diagnosed with Alzheimer's disease or another form of dementia. This situation only amplifies the disadvantages of arbitration. In addition, some commenters were concerned about arbitrator bias in favor of the facility. They were particularly concerned that a facility's ongoing need for arbitrators in subsequent cases could result in arbitrators issuing decisions favorable to the facility in order to receive future arbitral business from that facility.

Response: We understand that there are concerns about the fairness of the arbitral forum. Although no one can guarantee that every arbitrator will be neutral and fair in all arbitrations, comments we received caused us to conclude that arbitrators generally review the evidence submitted to them and make rational decisions based upon that evidence. While most state laws limit the circumstances upon which an arbitrator's decision can be challenged in court,[2] we believe that state laws regarding unconscionability or cohesion contracts offer some protection to residents from an arbitrator's decision if such a decision suggests bias towards the LTC facility. In addition, we are retaining the requirements that the facility must ensure that the arbitration agreement provides for the selection of a neutral arbitrator agreed upon by both parties and for the selection of a venue that is convenient to both parties. We are also finalizing the requirement at § 483.70(n)(5), which requires that when a facility resolves a dispute with a resident through arbitration, the facility must retain a copy of the signed arbitration agreement and the arbitrator's final decision for 5 years after the resolution of that dispute and make it available for inspection upon request from CMS or its designee. This requirement will enable us to determine how arbitration is being used by nursing homes and how residents are being treated in these arbitral forums. We believe that improving the transparency surrounding arbitration in nursing homes should also encourage facilities and arbitrators to treat residents fairly, if they are not currently doing so.

Comment: Some commenters disagreed with our proposal to require that the agreement be in plain language, be explained in a form and manner the resident understands, and that the facility receive an acknowledgement from the resident that he or she understands the agreement. They contended that these requirements did not eliminate or address what they saw as the fundamental problem: That a resident's decision to sign a pre-dispute, binding arbitration agreement could never be informed or voluntary without in-context knowledge of what is at stake. Some commenters asserted that the plain language requirement was useless, arguing that where pre-dispute, binding arbitration agreements are allowed as a condition of admission, it simply meant that it would be clear to the resident that he or she had no choice. Other commenters believed that the requirements for ''plain language'' were so vague and unclear that they would generate confusion. They also contended that the proposed rule would not support meaningful decision making by residents and its implementation would decrease residents' health, safety, and well-being. These commenters stated that the only way for the decision to sign an arbitration agreement to be voluntary and informed is if the resident was asked to sign it after the dispute has arisen. Many residents enter LTC facilities because they lack the ability to manage their day-to-day affairs. About half of LTC residents have been diagnosed with Alzheimer's disease or another form of dementia. The commenters are concerned that failure to explain the arbitration agreement to

[2] See 9 U.S. Code 10(a).

residents in a way that they understand the issue, could result in residents unwittingly signing an agreement to arbitrate with little understanding of the consequences of their action.

Response: After considering these comments, we agree with the commenters that the requirement for ''plain language'' is vague and could result in confusion. Therefore, we are not finalizing that proposed change to the requirements. As discussed above, we are also not finalizing the proposed change that would have allowed these agreements to be used as a condition of admission. However, we are retaining the requirement at § 483.70(n)(2)(i) and (ii) that the facility must ensure that the agreement be explained to the resident and his or her representative in a form and manner that he or she understand, including in a language the resident understands and the resident or his or her representative acknowledges that he or she understands the agreement. We believe these requirements are essential to ensure transparency in the arbitration process.

Comment: Some commenters were concerned about removing some of the specific requirements concerning arbitration or the arbitration agreement. For example, the proposed removal of the requirement that another individual could only sign for the resident if that individual had no interest in the facility and was authorized by state law to sign for the resident, could result in a person who is affiliated with the facility or has some type of interest in the facility signing for the resident. This would remove a critical protection for residents that may lack decision-making capacity. Others expressed concern about the possibility that residents and potential residents could have a family member, friend, or other personal contact affiliated with the facility.

Response: In drafting and entering into an arbitration agreement with its residents, LTC facilities must still comply with state law governing the rights of an individual to represent or legally bind a resident through a power of attorney or similar instrument. We are confident that state law would protect the rights of residents if someone signs one of these agreements without having the appropriate authority.

E. Costs

Comment: Some commenters pointed out the different advantages and disadvantages of arbitration. Some stated that arbitration results in faster, more flexible, less costly, and less adversarial resolution of disputes than litigation. One commenter quoted the 2016 final rule, ''arbitration agreements are, in fact, advantageous to both providers and beneficiaries because they allow for the expeditious resolution of claims without the costs and expense of litigation'' (82 FR 26651). One commenter cited an article that showed that in the context of labor-management disputes the costs of arbitration were less for lower-income employees (Elizabeth Hill, *Due Process at Low Cost: An Empirical Study of Employment Arbitration Under the Auspices of the American Arbitration Association,* 18 Ohio St. J on Disp. Resol. 777, 802 (2003)). They also pointed out that other advantages of arbitration included not needing an attorney, not having to show up at court since arbitration could be accomplished over the telephone or, perhaps, just submitting documents to the arbitrator. In addition, the commenter noted that reductions in funding to both federal and state courts could also lengthen the time needed to resolve a dispute through judicial proceedings. The commenter noted that arbitration proceedings do not have similar backlogs and can resolve disputes much faster.

However, there were also commenters pointed out that there were disadvantages. Some pointed out that arbitration could be more costly, especially for the resident. While LTC facilities may pay the costs for arbitration, this is not always the case. Since arbitration is a private process, there are costs for the venue, discovery, and the arbitrator. These costs can amount to thousands of dollars. It may also not result in a much faster or less adversarial resolution than litigation. In addition, some commenters contended that if arbitrators apply the applicable law incorrectly or make mistakes concerning what the appropriate law is for a particular claim and that state law generally limits the reasons for challenging the arbitrator's decision.

Privacy was another area in which commenters differed. Many commenters believed the secrecy of the arbitration process could be a disadvantage because LTC facilities could prevent disclosure of instances of poor or substandard care. However, another commenter, a non-profit provider, pointed out that some residents may not want to settle disputes in a court, especially disputes that involve physical or emotional injuries. Due to the relationship between non-profits and their residents, the residents may also prefer a less adversarial forum in which to settle disputes. Hence, judicial proceedings might not be preferable for all disputes.

Response: We agree with the commenters that arbitration has both advantages and disadvantages. Nonetheless, despite these claimed advantages and disadvantages, arbitration is an accepted form of dispute resolution and the FAA expresses a favorable view of arbitration. In addition, we agree that judicial proceedings may not be a preferable way for resolving all disputes. There are substantial hurdles to get a dispute into court. The resident must find an attorney willing to take the case. The attorney will generally decide to take a case based upon the potential damages and the difficulty of the case. If the attorney believes the case will be difficult to prove or that the damages are not adequate to justify the time and expense of judicial proceedings, he or she may not take the case. Cases of this nature would appear, therefore, to be good candidates for arbitration. Of course, there are also disadvantages to arbitration. It is not always faster or less expensive. In some cases, the costs associated with settling a dispute through arbitration could exceed those if the dispute was settled through judicial proceedings, especially for the resident or his or her representative. As commenters noted, settling a dispute in arbitration may not be faster. In addition, the losing party has limitations on contesting an arbitrator's decision in court. We acknowledge these advantages and disadvantages to arbitration and believe that the requirements in this final rule provide the transparency and opportunity for the resident and his or her representative to evaluate those advantages and disadvantages and make a choice that is best for them. This rule in no way would prohibit two willing and informed parties from entering voluntarily into an arbitration agreement.

Comment: Some commenters stated that prohibiting arbitration agreements would lead to more litigation and higher legal costs. These higher legal costs would result from increased insurance premiums and jury verdicts that would likely be higher than awards given in arbitration. One commenter cited a declaration from the AHCA litigation, that indicated that the insurer for Mississippi LTC facilities was likely to increase premiums if these arbitration agreements were not enforceable (*citing* Decl. of Suzanne Meyer at para. 14, *Am. Health Care Ass'n* v. *Burwell,* 217 F. Supp. 3d 921 (N.D. Miss. 2016) (No. 3:16–cv–00233), Dkt. No. 20–3). These higher legal costs could result in fewer resources for resident care and improving the quality of care for all residents. It would also increase the cost

of care, which would affect residents who are self-pay, their insurance companies, and government programs, especially Medicare and Medicaid.

Response: As discussed above, we are removing the prohibition on pre-dispute, binding arbitration agreements. Facilities are allowed to ask their residents to sign arbitration agreements so long as they comply with the requirements we are finalizing in this rule. This should address the commenters' concerns.

Comment: One commenter was concerned about higher costs to the facility as a result of the prohibition on pre-dispute, binding arbitration agreements. Since the amount of reimbursement from the Medicare and Medicaid programs is fixed, LTC facilities cannot raise their rates for residents whose care is paid for by those programs. Hence, LTC facilities could only cover higher costs by increasing the costs of care to residents who are paying for their care themselves and/or reduce the amount of resources that go to resident care. This could result in less care to all of the residents. Government programs could even face increased costs due to increased injuries or complications that result from poorer care.

Response: At this point, the evidence on the financial effects of prohibiting arbitration or allowing unfettered arbitration is anecdotal. However, the commenters tend to agree that when a claim is settled through arbitration, facilities save money. The resident advocacy groups contend that residents lose more often and, when they win, receive smaller awards than they would likely have had in judicial proceedings. LTC facilities assert that this same set of facts results in a positive financial impact because arbitration reduces their costs and ensures that more of their money can be spent on providing quality care to the residents. As discussed above, we are removing the prohibition on pre-dispute, binding arbitration agreements and permitting LTC facilities to enter into arbitration agreements if they comply with the requirements that are being finalized in this rule. We believe that the finalized requirements address these commenters' concern to a large extent.

Comment: Another commenter stated that arbitration prevents the government from seeking reimbursement for the costs of the resident's care related to any negligence by the LTC facility. Arbitration is not a public process and the government would not be made aware of any award by the arbitrator to a resident. Without notice, the government could not seek to recover any part of the cost of care to the resident as a result of any negligence or substandard care provided on the part of the facility from that award.

Response: We note that CMS generally does not seek to recover its costs from any award of damages to a resident when services are negligently provided. Instead, we enforce our health and safety standards through Requirements of Participation, Conditions of Participation, Conditions for Coverage, and the authority to terminate a negligent provider. For LTC facilities, we can also impose civil monetary penalties.

IV. Provisions of the Final Regulations

In this final rule, we are adopting the provisions in the June 8, 2017 proposed rule, with the following changes:

- Revised § 483.70(n)(1) to specify that a facility must not require any resident or his or her representative to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue receiving care at, the facility and must explicitly inform the resident or his or her representative of his or her right not to sign the agreement as a condition of admission to, or as a requirement to continue receiving care at, the facility.
- Removed § 483.70(n)(1)(i).
- Redesignated § 483.70(n)(1)(ii) and (iii) as § 483.70(n)(2)(i) and (ii).
- Revised the redesignated § 483.70(n)(2)(ii) to specify that the facility must ensure that the resident or his or her representative acknowledge that he or she understands the agreement.
- Added § 483.70(n)(2)(iii) to specify that the agreement provides for the selection of a neutral arbitrator agreed upon by both parties.
- Added § 483.70(n)(2)(iv) to specify that the agreement provides for the selection of a venue that is convenient to both parties.
- Redesignated § 483.70(n)(2) as § 483.70(n)(5).
- Redesignated § 483.70(n)(3) as § 483.70(n)(6).
- Added § 483.70(n)(3) to specify that the agreement must explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it.
- Revised § 483.70(n)(4) to state that an arbitration agreement must explicitly state that neither the resident nor his or her representative is required to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility.
- Revised redesignated § 483.70(n)(6) to read that when a facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years after resolution of that dispute and be available for inspection upon request by CMS or its designee.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 PRA 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.

Omnibus Budget Reconciliation Act of 1987 Waiver

Ordinarily, we are required to estimate the public reporting burden for information collection requirements for this regulation in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100–204) provide for a waiver of the PRA requirements for this regulation. Thus, we have not provided an estimate for any paperwork burden related to these revisions and additions.

VI. Regulatory Impact Statement

A. Statement of Need

The district court's decision in granting the preliminary injunction against enforcement of the prohibition on pre-dispute, arbitration agreements indicated that CMS would at a minimum face some substantial legal hurdles from pursuing the arbitration policy set forth in the 2016 final rule. We have reviewed the provisions and determined that the arbitration requirements should be revised. We believe that the protections for residents that we have finalized in this rule strike a better balance of competing policy

concerns. The revisions to these requirements in the 2017 final rule will increase transparency in LTC facilities that chose to use arbitration while, at the same time, allowing facilities to use arbitral forums as a means of resolving disputes.

B. Overall Impact

The overall impact of this final rule is to provide transparency in the arbitration process in nursing homes to the residents, his or her family and representatives, and the government. It also ensures that no resident will be required to sign a pre-dispute, binding arbitration agreement as a condition for receiving the care he or she needs. In addition, by ensuring that the resident has the right to rescind the agreement within 30 calendar days of signing it, residents can get beyond the admissions process and have adequate time to consider the agreement and get legal advice.

We have examined the impact 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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief 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 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an 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 the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, the UMRA threshold is approximately $154 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

C. Cost to the Federal Government

We do not believe that these revisions would impose any additional costs.

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the number of commenters on the proposed rule is the number of reviewers who will thoroughly review the final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible or even likely that not all of those prior reviewers will extensively reread this rule, and may instead focus on changes to the regulatory text or only specific responses to comments. On the other hand, it is conceivable that there may be more than one individual reviewing the rule for some of the affected entities, or that many entities thoroughly reviewed the rule without commenting. For those reasons, we thought that the number of commenters on the proposed rule would be a fair estimate of the number of reviewers of this rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of some final rules, or that some entities may not find it necessary to fully read each rule, 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 Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/2017/may/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take 0.65 hours for the staff to review half of this final rule. For each entity that reviewed the rule, the estimated cost is $69.80 (0.65 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $70,000 ($69.80 × 1,020 reviewers).

E. Executive Order 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' OMB's interim guidance, issued on April 5, 2017, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf,* explains that for Fiscal Year 2017 the above requirements only apply to each new ''significant regulatory action that imposes costs.'' It has been determined that this final rule is an action that does not impose more than de minimis costs and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

F. Benefits of the Rule

With the exception of the requirement that facilities post notices of their

arbitration policies, the requirements finalized in this rule maintain the transparency requirements promulgated in the 2016 final rule. Specifically, this rule ensures that LTC facilities must make every effort to inform the resident of the nature and existence of any proposed arbitration agreement. The agreement must be explained to the resident in a form and manner he or she understands and the must resident acknowledge that he or she understands the agreement. Additionally, we are retaining the requirement that the agreement may not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials.

We believe that these transparency requirements address many stakeholder concerns regarding the fairness of arbitration in LTC facilities. These requirements also support the resident's right to make informed choices about important aspects of his or her healthcare and ensure that we can protect resident health and safety.

We have also finalized the requirement that, when a facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years after the resolution of that dispute and also be available for inspection by CMS or its designee. This requirement will provide CMS an opportunity to gather data about the extent to which quality of care issues are addressed in arbitration, to ensure that quality of care concerns that are the subject of arbitration can be thoroughly investigated, if needed, in specific cases, or in aggregate, and the overall impact that arbitration may have on residents of LTC facilities. Based on the comments we received, we have also added a requirement that the agreement must explicitly grant the resident the right to rescind the agreement within 30 calendar days of signing it. This provides the resident approximately one month to adjust to the LTC facility, consider and understand the implications of the agreement, and, if he or she desires, seek legal advice about rescinding the agreement.

In addition, based on comments we received, we are not finalizing the proposal to allow facilities to use pre-dispute, binding arbitration agreements as a condition of admission to the facility. As discussed above, residents, their families, and caregivers consider various factors in choosing a LTC facility. We doubt that one of those potential factors, whether a nursing home requires signing a pre-dispute, binding arbitration agreement as a condition of admission, is often a deciding factor for residents, caregivers, or representatives. This is especially important since the choice of nursing homes may be limited based on various factors. This requirement will enable residents, their families, and caregivers to choose a LTC facility based upon what is best for the resident's health and safety without having to be required to sign a pre-dispute, binding arbitration agreement. It will also ensure that no resident, his or her family, or caregiver will have to decide between signing this type of agreement and the resident receiving the care he or she needs.

G. Alternatives Considered

As discussed above, the district court granted a preliminary injunction against enforcement of the prohibition against pre-dispute, binding arbitration agreements. We considered removing all of the arbitration requirements and returning to the position in the previous requirements, that is, the requirements would be silent on arbitration. We also considered continuing to defend the 2016 regulation. While we do not agree with the district court's decision, it provided us the opportunity to explore other ways to balance the interests of LTC facilities that wish to arbitrate claims with the need to ensure that LTC residents have the ability to make an informed decision about whether or not to sign an arbitration agreement and resolve issues when necessary in the best and most reasonable way they see fit.

In light of the comments we received, we have determined that such a balance can be struck by removing the prohibition of pre-dispute, binding arbitration agreements while maintaining and modifying the transparency requirements promulgated in the 2016 regulation. The comments we received demonstrated that many LTC residents are not aware they have signed an arbitration agreement until after a dispute arises. We have concluded, therefore, that transparency is essential, and that CMS may properly exercise its statutory authority to ensure transparency under its statutory authority to promote the health and safety of LTC residents. Consequently, with the exception of posting notices and requiring ''plain language,'' we have retained those requirements that provide for transparency. We are also not finalizing our proposal that would have allowed facilities to use pre-dispute, binding arbitration agreements as a condition of admission to, or a requirement to continue to receive care at, the facility for the reasons discussed above. We believe the finalized requirements will provide sufficient transparency to protect residents' health and safety, including supporting their right to make informed decisions about their health care. These finalized requirements should also alleviate many of the residents and advocates' concerns about the arbitration process while also allowing LTC facilities to arbitrate claims should they so choose.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subject in 42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 1. The authority citation for part 483 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 2. Section 483.70 is amended by revising paragraph (n) to read as follows:

§ 483.70 Administration.

* * * * *

(n) *Binding arbitration agreements.* If a facility chooses to ask a resident or his or her representative to enter into an agreement for binding arbitration, the facility must comply with all of the requirements in this section.

(1) The facility must not require any resident or his or her representative to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility and must explicitly inform the resident or his or her representative of his or her right not to sign the agreement as a condition of admission to, or as a requirement to continue to receive care at, the facility.

(2) The facility must ensure that:

(i) The agreement is explained to the resident and his or her representative in a form and manner that he or she understands, including in a language the resident and his or her representative understands;

(ii) The resident or his or her representative acknowledges that he or she understands the agreement;

(iii) The agreement provides for the selection of a neutral arbitrator agreed upon by both parties; and

(iv) The agreement provides for the selection of a venue that is convenient to both parties.

(3) The agreement must explicitly grant the resident or his or her representative the right to rescind the agreement within 30 calendar days of signing it.

(4) The agreement must explicitly state that neither the resident nor his or her representative is required to sign an agreement for binding arbitration as a condition of admission to, or as a requirement to continue to receive care at, the facility.

(5) The agreement may not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k).

(6) When the facility and a resident resolve a dispute through arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years after the resolution of that dispute on and be available for inspection upon request by CMS or its designee.

* * * * *

Dated: February 6, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: February 13, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Editorial Note: This document was received by the Office of the Federal Register on July 10, 2019.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 482, 483, 485 and 488

[CMS–3347–P]

RIN 0938–AT36

Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform the Medicare and Medicaid long-term care requirements that the Centers for Medicare & Medicaid Services has identified as unnecessary, obsolete, or excessively burdensome. This rule would increase the ability of health care professionals to apportion resources to improving resident care by eliminating or reducing requirements that impede quality care or that divert resources away from providing high quality care.

DATES: To be assured consideration, comments must be received at one of the addresses provided, no later than 5 p.m. on September 16, 2019.

ADDRESSES: In commenting, please refer to file code CMS–3347–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3347–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3347–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: LTC Regulations Team, Ronisha Blackstone, Diane Corning, Mary Collins, Kristin Shifflett, Eric Laib, Lisa Parker, and Sheila Blackstock at (410) 786–6633.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

Over the past several years, we have revised the Conditions of Participation (CoPs), the Conditions for Coverage (CfCs), and requirements for long-term care (LTC) facilities to reduce the regulatory burden on providers and suppliers. We identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and states could use to improve and enhance resident health and safety. We have also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for residents, while reducing burden on providers and suppliers of care, and we identified non-regulatory changes to increase transparency and to become a better business partner. In addition, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) have reaffirmed their shared commitment to the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objectives are to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the healthcare marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.

We are proposing changes to the current LTC requirements and survey process that would simplify and streamline the current requirements and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing facilities to focus on providing high-quality healthcare to their residents. This proposed rule would also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain facility requirements and remove obsolete, duplicative, or unnecessary requirements. We believe that these proposals balance resident safety and quality of care, while also providing regulatory relief for facilities.

2. Summary of Major Provisions

a. Requirements for Participation

Resident Rights (§ 483.10)

We propose to revise the requirement for facilities to ensure that residents remain informed of the name and specialties of the physician and other primary care professionals responsible for their care, and is provided with their contact information. Specifically, we propose to reduce burden by revising the provision to require facilities to provide residents with their primary care physician's name and contact information upon admission, with any change, or upon a resident's request.

In addition, we propose revisions to the grievance policy requirements. Proposed revisions include clarifying that general feedback may not rise to the level of an official grievance, removing the specific duties required of the grievance official, removing prescriptive requirements related to written grievance decisions, and reducing the amount of time that facilities must retain evidence demonstrating the results of grievances from 3 years to 18 months.

Admission, Transfer, and Discharge Rights (§ 483.15)

We propose to revise the requirement for facilities to send discharge notices to State LTC Ombudsman by applying this requirement to ''facility-initiated involuntary transfers and discharges'' only. This proposed revision would reduce the paperwork burden on facilities.

Quality of Care (§ 483.25)

We propose to modify requirements to focus on the appropriate ''use'' of bed

rails and eliminate references to the ''installation'' of bed rails. These revisions would provide clarity and address stakeholder concerns regarding the purchase of beds with bed rails already in place with no practical means of removal.

Nursing Services (§ 483.35)

We propose to reduce the timeframe that LTC facilities are required to retain posted daily nursing staffing data from 18 months to 15 months, or as required by state law. The proposed revision would reduce a paperwork burden on facilities.

Behavioral Health (§ 483.40)

We propose to remove requirements that are duplicative of other LTC requirements in other sections of the regulation, and improve clarity.

Pharmacy Services (§ 483.45)

We propose to remove the existing requirement that Pro re Nata (PRN), or as needed, prescriptions for anti-psychotics cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication. This proposed revision would increase flexibility by allowing each facility to allow for PRN orders of all psychotropic medications to be extended beyond 14 days if the attending physician or prescribing practitioner believes it appropriate and documents his or her rationale in the resident's medical record and indicates the duration for the PRN order. We have also solicited specific comments concerning this proposed modification.

Food and Nutrition Services (§ 483.60)

We propose to revise the required qualifications for a director of food and nutrition services to provide that those with several years of experience performing as the director of food and nutrition services in a facility could continue to do so. We propose that at a minimum an individual designated as the director of food and nutrition services would receive frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional; and would either have 2 or more years of experience in the position of a director of food and nutrition services, or have completed a minimum course of study in food safety that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, food purchasing/receiving, etc. This proposal would help to address concerns related to costs associated with training for existing staff and the potential need to hire new staff.

Administration (§ 483.70)

We propose to clarify that data collected under the facility assessment requirement can be utilized to inform policies and procedures for other LTC requirements. In addition, we propose to remove duplicative requirements and revise the requirement for the review of the facility assessment from annually to biennially.

Quality Assurance and Performance Improvement (§ 483.75)

We propose to revise the requirement for facilities to implement a Quality Assurance and Performance Improvement (QAPI) program by removing prescriptive requirements to allow facilities greater flexibility in tailoring their QAPI program to the specific needs of their individual facility.

Infection Control (§ 483.80)

We propose to remove the requirement that the infection preventionist (IP) work at the facility ''part-time'' or have frequent contact with the infection prevention and control program (IPCP) staff at the facility. We will instead require that the facility must ensure that the IP has sufficient time at the facility to meet the objectives of its IPCP. We will also include comment solicitations on this proposal.

Compliance and Ethics Program (§ 483.85)

We propose to remove many of the requirements from this section not expressly required by statute. Proposed revisions include removing the requirements for a compliance officer and compliance liaisons and revising the requirement for reviewing the program from annually to biennially.

Physical Environment (§ 483.90)

We propose to allow older existing LTC facilities to continue to use the 2001 Fire Safety Equivalency System (FSES) mandatory values when determining compliance for containment, extinguishment, and people movement requirements. This proposal would allow older facilities who may not meet the FSES requirements in the recently adopted 2012 Life Safety Code (LSC) to remain in compliance with the older FSES without incurring substantial expenses to change their construction types, while maintaining resident and staff safety.

In addition, we propose to revise the requirements that newly constructed, reconstructed, or newly certified facilities accommodate no more than two residents in a bedroom and equip each resident room with its own bathroom that has a commode and sink.

Specifically, we propose to only apply this requirement to newly constructed facilities and newly certified facilities that have never previously been a nursing home. This would remove unintended disincentives to purchase facilities or make upgrades to existing facilities.

Technical Corrections

We propose to correct several technical errors that have been identified in 42 CFR part 483 subpart B.

b. Survey, Certification, and Enforcement Procedures

Informal Dispute Resolution and Independent Informal Dispute Resolution (§ 488.331 and § 488.431)

We propose to revise the informal dispute resolution and independent informal dispute resolution processes to increase provider transparency by ensuring that administrative actions are processed timely, and that providers understand the outcomes of results.

Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

We propose to eliminate the requirement for facilities to actively waive their right to a hearing in writing and create in its place a constructive waiver process that would operate by default when CMS has not received a timely request for a hearing. The accompanying 35 percent penalty reduction would remain. This proposed revision would result in lower costs for most LTC facilities facing civil money penalties (CMP)s, and would streamline and reduce the administrative burden for stakeholders.

Phase 3 Implementation of Overlapping Regulatory Provisions

The revised LTC requirements for participation are being implemented in three phases. Phases 1 and 2 were implemented in November of 2016 and 2017, respectively. Phase 3 includes additional regulatory provisions that are scheduled to be implemented on November 28, 2019.

Of the Phase 3 provisions, this regulation proposes revisions that, if finalized, would have an impact on provisions that fall into three primary areas—(1) designation and training of the infection preventionist (§ 483.80), QAPI (§ 483.75), and compliance and

ethics program (§ 483.85). We propose to delay implementation of some these Phase 3 provisions until 1 year following the effective date of this regulation. We do not propose to delay those requirements related to the infection preventionist at § 483.80(b)(1) through (4), (c) and § 483.75(g)(1)(iv). This would avoid unnecessary work, confusion and burden associated with implementing provisions, which may then change in a final rule shortly thereafter.

3. Summary of Costs and Benefits

In this proposed rule we have identified reforms in more than a dozen major sections of the existing Code of Federal Regulations (CFR) pertaining to LTC facilities. Every proposed reform aims to reduce regulatory burdens on these facilities without jeopardizing any responsibilities or practices that maintain or improve resident care. The ''benefits'' of this proposed rule are its cost reductions, and there are no known ''costs'' imposed by this regulation. Our proposals and these conclusions are explained throughout this preamble, and we welcome additional information on each, suggested improvements, additional reform proposals, and any other comments.

In total, we have identified and proposed reductions in information collection burden whose annual costs today, and future annual savings will be approximately $59 million. We propose other reforms in current regulations that will generate annual savings in operating costs of almost $210 million. We also propose reducing punitive facility construction requirements that will save in excess of $325 million in costs over each of the next 5 years. Total estimated cost savings over each of the first 5 years are approximately $616 million.

B. Background

1. Statutory and Regulatory Authority of the Long-Term Care Requirements

The provisions contained in this proposed rule are authorized by the general rulemaking authority for the Secretary of the Department of Health and Human Services (the Secretary) under sections 1102 and 1871 of the Act, which afford the Secretary broad authority to promulgate such regulations as may be necessary to administer the Medicare and Medicaid programs.

In addition, the Secretary has statutory authority to issue these rules under the Nursing Home Reform Act, (part of the Omnibus Budget Reconciliation Act of 1987 (''OBRA '87''), (Pub. L. 100–203, 101 Stat. 1330 (1987)), which added sections 1819 and 1919 to the Act; those provisions authorize the Secretary to promulgate regulations that are ''adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.'' (Sections 1819(f)(1) and 1919(f)(1) of the Act). In addition, the Act authorizes the Secretary to impose ''such other requirements relating to the health and safety [and well-being] of residents as [he] may find necessary.'' (Sections 1819(d)(4)(B), 1919(d)(4)(B) of the Act). Under Sections 1819(c)(1)(A)(xi) and 1919 (c)(1)(A)(xi) of the Act, the Secretary may also establish ''other right[s]'' for residents, in addition to those expressly set forth in the statutes and regulations, to ''protect and promote the rights of each resident.''

Section 1864(a) of the Act authorizes the Secretary to enter into agreements with state survey agencies (SAs) to determine whether facilities meet the Federal participation requirements for Medicare. Section 1902(a)(33)(B) of the Act provides for SAs to perform the same survey tasks for facilities participating or seeking to participate in the Medicaid program. The results of Medicare and Medicaid related surveys are used by Centers for Medicare and Medicaid Services (CMS) and the State Medicaid agency, respectively, as the basis for a decision to enter into or deny a provider agreement, recertify facility participation in one or both programs, or terminate the facility from the program. They are also used to determine whether one or more enforcement remedies should be imposed where noncompliance with federal requirements is identified.

2. October 2016 Long-Term Care Final Rule

On October 4, 2016, we issued a final rule entitled, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (81 FR 68688). This final rule significantly revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. Prior to the final rule, the LTC requirements had not been comprehensively reviewed and updated since 1991 (56 FR 48826, September 26, 1991), despite substantial changes in service delivery in this setting. The final rule included revisions that reflect advances in the theory and practice of service delivery and safety. In addition, the various revisions sought to achieve broad-based improvements in the quality of care provided in LTC facilities and in resident safety.

We received mixed reactions from LTC stakeholders in response to our revision of the LTC requirements. Overall, all stakeholders supported the regulation's focus on person-centered care and agreed that reforms to the existing requirements were necessary to support high quality care and quality of life in LTC facilities. While supportive of the goals of the regulation, some industry stakeholders noted that some of the changes needed to comply with the revised requirements would be costly and burdensome. Given the scope of the revisions, stakeholder requests for more time to comply with the requirements, and the financial impact that the regulation would impose on LTC facilities, we finalized a phased-in implementation of the requirements over a 3-year time period with the goal of reducing some of the burden placed on LTC facilities. Readers may refer to the October 2016 final rule (81 FR 68696) for a detailed discussion regarding the implementation timeframes for the requirements. In addition, we established an 18-month transition period for facilities who fall short on complying with the November 28, 2017 implementation of the Phase 2 Requirements of Participation. There would be a temporary 18-month moratorium on the imposition of civil money penalties, discretionary denials of payment for new admissions and discretionary termination where the remedy is based on a deficiency finding of the certain Phase 2 requirements; however, facilities would be required to invest in staff education and to come into compliance as quickly as possible (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf*).

3. Comment Solicitation in the Fiscal Year (FY) 2018 Skilled Nursing Facility Prospective Payment System (SNF PPS) Proposed Rule

In the FY 2018 Skilled Nursing Facility Prospective Payment System (SNF PPS) proposed rule (82 FR 21014) published in the **Federal Register** on May 4, 2017, we solicited comments for feedback regarding areas of burden reduction and cost savings in LTC facilities. We received 184 public comments in response to our request for comments. Commenters included LTC facilities, LTC consumers, LTC advocacy groups, many individual healthcare professionals, and various health care organizations and associations.

In the FY 2018 SNF PPS proposed rule we also discussed potential areas for burden reduction including

revisions to the grievance policy requirements, (§ 483.10(j)), the Quality Assurance and Performance Improvement (QAPI) program (§ 483.75), and removing the requirement that discharge notices be sent to the LTC Ombudsman (§ 483.15). Commenters also provided additional suggestions for burden reduction. The majority of the additional suggestions were related to removing the requirement for a facility assessment and increasing the timeframe associated with reporting suspicions of resident abuse. One commenter provided a detailed financial analysis of their costs so far related to implementing their QAPI, Infection Control, and Compliance and Ethics programs. We also received additional comments related to the survey process and requirements for providing payroll-based journal data at § 483.75(u) (as implemented in the August 4, 2015 final rule entitled, ''Medicare Program; Prospective Payment System (PPS) and Consolidated Billing for Skilled Nursing Facilities (SNF) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (80 FR 46389). Furthermore, several commenters also recommended that we not revise the requirements for purposes of reducing burden on facilities at the expense of the safety and quality of care provided to residents. These commenters noted that the true impact of the requirements cannot be assessed, as the majority have not yet been implemented.

In combination with our internal review of the existing regulations, we have used stakeholder feedback to inform our policy decisions with regard to the proposals discussed in this rule. We note that we considered all of the stakeholder recommendations and specifically considered how each recommendation could potentially reduce burden without impinging on the health and safety of residents. In addition, we note that we are committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on person-centered care and working with providers, physicians, and residents to improve outcomes. We seek to reduce burdens for facilities and residents, improve the quality of care, decrease costs, and ensure that residents, their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction. We specifically are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on facilities and create cost savings, while also preserving quality of care and resident health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

II. Provisions of the Proposed Regulations

A. Requirements for Participation

1. Resident Rights (§ 483.10)

Choice of Attending Physician

Section 483.10(d)(3) requires that facilities ensure that a resident remains informed of the name and specialties of the physician and other primary care professionals responsible for his or her care, and is provided with their contact information. While understanding that residents are often under the care of multiple healthcare professionals, we can see how this requirement could have the potential to substantially burden facilities with maintaining an exhaustive list of professionals for each resident. In addition, we understand that the use of ''remain informed'' is vague and may impose unnecessary burdens on both the facility and residents to meet this requirement. Therefore, we propose to revise this provision to remove the language indicating that facilities must ensure that residents remain informed and would instead specify that residents be informed of only their primary care physician's information at admission, with any change of such information, and upon the resident's request. We believe that this proposal clarifies the intent of the requirement, which is to ensure that a resident knows the name and contact information for the individual(s) primarily responsible for their care. The revision would ultimately reduce burden on facilities by specifically detailing their responsibilities under this requirement. We request additional feedback from LTC stakeholders regarding the need for residents to receive contact information for providers responsible for their care outside of their primary care physician, such as a psychiatrist or physical therapist, and how to contact that provider. Specifically, we are interested to learn how residents are typically provided with this information and whether it is a standard practice for the primary care physician or facilities to maintain and provide this type of contact information to residents.

Grievances

The October 2016 final rule finalized a proposal at § 483.10(j) to extensively expand the grievance process in LTC facilities. Specifically, facilities are required to establish a grievance policy to ensure the prompt resolution of grievances and identify a grievance officer to oversee the process. LTC stakeholders have supported the enhancement of residents' rights to voice grievances and emphasize the importance and seriousness of resident concerns. However, other industry stakeholders have also indicated that the expansion of the requirements for a grievance process is overly burdensome and costly, specifically with regard to maintaining evidence related to grievances, and staffing a grievance official.

After further consideration, we believe that revisions can be made to these requirements to minimize prescriptiveness, while maintaining facility accountability. We are also requesting additional feedback regarding how to minimize burden while taking into account the rights of residents, and the additional burden on residents and long-term care ombudsmen if the proposed revisions to the requirements at § 483.10(j) are made. Specifically, we propose to revise § 483.10(j)(1) by adding language that would clarify the difference between resident feedback and a grievance. Section 483.10(j)(1) would be revised to state that the resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment which have been furnished as well as those which have not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay that differ from general feedback provided by the resident or their resident representatives. We believe that the addition of this language would help to streamline a facility's grievance process and ensure that the grievance process focuses on concerns that rise to the level of an official grievance. We believe that a streamlined process would increase efficiency and facility response to grievances, which will have a positive impact on a resident's ability to voice

their grievances and have them resolved promptly. Furthermore, we believe that general feedback or complaints stem from general issues that can typically be resolved by staff present at the time a concern is voiced, while grievances are more serious and generally require investigation into allegations regarding the quality of care. It would be the facility's responsibility to include how they made this determination as to whether a comment was a grievance or general feedback as part of their grievance policy and ensure that residents were fully informed of such determination.

We believe that the added language provides clarification without impeding on a resident's right to voice grievances. However, we want to emphasize that a resident's right to voice grievances and a facility's responsibility to make prompt efforts to resolve grievances fully remains. We expect that in the event a facility has not addressed general feedback provided repeatedly by a specific resident, or the same feedback filed by different residents, such lack of a resolution by the facility would raise their concerns to that of a grievance. Therefore, we would expect that as a general practice, facilities would continue to make every effort to resolve resident concerns before the grievance process is initiated. Nonetheless, we note that certain systems continue to be in place if a resident believes that their rights have been ignored or not appropriately addressed by the facilities. These include raising their concerns through the Ombudsman program, State Survey Agency, or the Quality Improvement Organization (QIO) program.

We also propose to revise § 483.10(j)(2) to remove the phrase ''by the facility.'' The revision would read as follows, ''the resident has the right to, and the facility must make prompt efforts to, resolve grievances the resident may have, in accordance with this paragraph.'' We believe that this revision does not make any substantive changes, but would remove unnecessary language and improve readability. The facility's responsibility to make prompt efforts to resolve resident grievances fully remains.

At § 483.10(j)(4)(ii), we propose to remove the specific duties required of the grievance official who is responsible for overseeing the grievance process. We believe that this revision would address facility stakeholder concerns by allowing facilities greater flexibility in determining how their individual facility will ensure grievances are fully addressed. We note that facilities have the flexibility to assign the role of grievance official to existing staff, and the existing requirements do not prohibit facilities from assigning multiple or additional individuals to assist the grievance official in the oversight of the facility's grievance process. We do not believe that this proposal will have a negative impact on residents because residents will still have a specific individual(s) to directly report to their grievances. In addition, existing requirements at § 483.10(j)(3) also require facilities to make information on how to file a grievance or complaint available to the resident. This proposal does not impede on a resident's right to voice grievances, but rather removes prescriptiveness and allows facilities some flexibility in delegating the responsibilities of the grievance official.

Section 483.10(j)(4)(v) requires facilities to ensure that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concern(s), a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued. We propose to revise § 483.10(j)(4)(v) to require facilities to ensure that any written grievance decisions include any pertinent information including but not limited to a summary of the findings or conclusions and any corrective actions. We expect that information, such as the date the grievance was received and a summary statement of the resident's grievance, is included as a standard practice to ensure that the written decision is complete and informative. This revision would remove much of the specificity included in the provision in an effort to focus on the true intent of the requirement, which is to clearly inform residents of grievance decisions and any corrective actions.

Lastly, we propose to revise § 483.10(j)(4)(vii), to require facilities to maintain evidence demonstrating the results of all grievances for a period of no less than 18 months from the issuance of the grievance decision. We are not proposing to remove the requirement to maintain records because we believe that record retention related to grievances protects both facilities and residents. Instead, we are proposing a timeframe of 18 months, as this time period would cover the longest possible interval between surveys for a facility (plus a few months) and provide a sufficient amount of information for investigations during a survey. Reducing this timeframe to 18 months from the existing requirement of 3 years, would uphold facility accountability while reducing the burden associated with maintaining records.

We request additional feedback regarding any unintentional consequences related to shortened timeframes for record retentions and whether there may be a need to retain records of grievances longer than a survey cycle.

2. Admission, Transfer, and Discharge Rights (§ 483.15)

Regulations at § 483.15(c)(3)(i) require LTC facilities to send transfers or discharge notices to the State LTC Ombudsman. As part of the FY 2018 SNF PPS proposed rule comment solicitation as previously discussed (82 FR 21014) we received valuable feedback from LTC stakeholders, including representatives of various Offices of State Long-Term Care Ombudsman, regarding a LTC Ombudsman's capacity to receive and review these notices. Stakeholders have indicated that there are some states that currently require involuntary discharge notices to be shared with the State LTC Ombudsman offices with requirements outlined for notification.

We also received valuable feedback with regard to the extent that a LTC Ombudsman will use this information once received. Stakeholders indicated that LTC Ombudsman programs are currently receiving notices and use the information to help individual residents, track trends, and advocate for systems changes to reduce inappropriate discharges.

After considering all of the feedback received and re-evaluating this requirement, we believe that the requirement is valuable; however, further clarification in the requirements is necessary to achieve the intended objective of reducing inappropriate discharges. Therefore, we propose to revise § 483.15(c)(3)(i) to specify that facilities must send a copy of a transfer or discharge notice to a representative of the Office of the State Long-Term Care Ombudsman only in the event of facility-initiated involuntary transfers or discharges. We note that this would not include residents who request the transfer, or who are transferred, on an emergency basis to an acute care facility when return is expected. We are soliciting comments on whether the requirement to send copies of transfer notices to the LTC Ombudsman should apply to transfers made on an emergency basis to an acute care facility, regardless of return status and

how this information, when a resident is expected to return, may be beneficial.

Furthermore, by ''facility-initiated'' involuntary transfer or discharge we mean a transfer or discharge that the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences. We encourage readers to refer to the Interpretive Guidance for additional information regarding when this requirement does and does not apply at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.*

We believe that this revision continues to support our goal of protecting residents in instances of involuntary transfers and discharges and reduces burden by streamlining the notification process to focus only on involuntary transfers or discharges. Streamlining this requirement would also improve resident access to the services of the Ombudsman program to assist during the discharge process by allowing Ombudsman offices to focus directly on inappropriate and involuntary discharges by facilities.

3. Quality of Care (§ 483.25)

Regulations in § 483.25 set forth requirements for numerous aspects of care and special needs of LTC facility residents. Regulations at § 483.25(n) require facilities to attempt to use appropriate alternatives prior to installing a side or bed rail. Section 483.25(n)(1) through (4) specifies requirements for when a facility uses bed or side rails. Specifically, facilities must ensure correct installation, use and maintenance of bed rails, including assessing the resident for the risk of entrapment from bed rails prior to installation, reviewing the risks and benefits of bed rails with the resident and obtaining informed consent prior to installation, ensuring that the resident's size and weight are appropriate for the bed's dimensions, and following the manufacturers' recommendations and specifications for installing and maintaining bed rails.

We received several inquiries from LTC stakeholders, as well as surveyors regarding these requirements and CMS' intent. Specifically, stakeholders have indicated that often times beds are purchased with bed rails already installed. In these instances, industry stakeholders are concerned with the inspection requirements ''prior to installation,'' specifically whether they are required to remove these bed rails or whether they can remain on beds, but not in use. Furthermore, if removal is required industry stakeholders have shared concerns regarding warranty agreements and surveyors have questioned how to evaluate compliance in these instances.

We agree that revisions are necessary to improve clarity. Given the potential risks associated with the use of bed rails, including accident hazards and physical restraint, this requirement is intended to ensure that facilities attempt alternatives prior to installing bed rails and ensure that resident safety is considered if/when they are being used. To clarify this, we propose to revise § 483.25(n) to remove references to the ''installation'' of bed rails and replace them with the ''use'' of bed rails. These revisions would focus on the appropriate use of bed rails when alternatives to bed rails are not feasible and address concerns related to the use of beds with bed rails already installed.

4. Nursing Services (§ 483.35)

Regulations in § 483.35 address certain aspects of LTC facility staffing and the need to consider the competencies of staff and resident acuity. Regulations at § 483.35(g) require facilities to post daily nurse staffing data that includes, among other information, the total number and the actual hours worked by licensed and unlicensed nursing staff directly responsible for resident care per shift. Section 483.35(g)(4) requires facilities to maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by state law, whichever is greater. We understand that some industry stakeholders believe that the new requirements for payroll-based journal (PBJ) staffing reporting at § 483.70(g) may be similar to the requirement at § 483.35(g)(4). Specifically, regulations at § 483.70(g) require facilities to electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

These regulations differ in that the requirements at § 483.70(g) provide a retrospective reporting of staffing so consumers can understand the type of staffing that exists in a facility on an average day, while the requirements at § 483.35(g) of daily postings provide real time information for residents and their families so that they are informed of who is working and the amount of staff working in their facility during a specific shift.

Therefore, we believe that both requirements are necessary. However, we believe that we may provide some flexibility in the regulations at § 483.35(g)(4) regarding the timeframe for retaining the posted information. We propose to revise § 483.35(g)(4) by reducing the timeframe for the retention of the nurse staffing data from 18 months to 15 months. We believe that 15 months of this facility-stored data would be sufficient to support any potential surveyor investigations.

5. Behavioral Health (§ 483.40)

Regulations at § 483.40 require facilities to provide the necessary behavioral health care and services for their residents to attain or maintain their highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health is defined as encompassing a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders. Facilities must also have sufficient staff who provide direct services to the residents with the appropriate competencies and skill sets to provide nursing and related services. LTC stakeholders have recommended that we eliminate this section entirely or reconsider the requirements to address burden and avoid turning LTC facilities into mental health institutions. LTC stakeholders have also indicated that the regulations lack clarity and noted that there may be duplication of the requirements in this section elsewhere.

In further reviewing § 483.40, we continue to believe that a focus on the care and treatment for residents with mental disorders or psychosocial adjustment difficulties is necessary. Therefore, we are not proposing to eliminate this section, as suggested by some stakeholders. However, during our review of these requirements we identified areas of duplication that could be eliminated. We are proposing revisions to this section to improve clarity and ensure that our regulations clearly reflect what we require from facilities.

Specifically, § 483.40(a) requires facilities to have sufficient staff who provide direct services to residents with the appropriate competencies and skill sets to provide nursing and related services, in accordance with a facility's assessment (§ 483.70(e)). This requirement duplicates the requirements at § 483.35, ''Nursing Services,'' which specify the general requirements for sufficient staff. To simplify the overall requirement, we propose to remove the duplicative language in § 483.40(a). This revision

would clearly articulate the intent of this requirement, which is to inform facilities of their responsibility to provide sufficient staff members who possess the basic competencies and skills sets to meet the behavioral health needs of residents for whom the facility has assessed and developed care plans.

Likewise, in further reviewing this section we have determined that § 483.40(c) is identical to the requirements in § 483.65(a), ''Specialized Rehabilitative Services.'' Therefore, we are proposing to remove § 483.40(c) from this section.

In addition, to these proposed revisions, we encourage those stakeholders seeking further clarity regarding the implementation of the Behavioral Health requirements, as well as the other regulatory sections, to look to the Interpretive Guidelines as a valuable resource. On June 20, 2017, CMS released Interpretive Guidelines for the LTC requirements for participation (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf*), which were developed with input from a variety of stakeholders including industry, clinical, and advocacy organizations.

6. Pharmacy Services (§ 483.45)

The existing regulations at § 483.45(e)(4) require that PRN prescriptions for psychotropic drugs be limited to 14 days. However, if the attending physician or prescribing practitioner believes it is appropriate for a PRN prescription order to be extended beyond 14 days, he or she may document their rationale in the resident's medical record and indicate the duration of the PRN order. However, that exception does not extend to anti-psychotics, which are limited to 14 days, unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication, as set forth at current § 483.45(e)(5).

We received feedback from the provider community concerning the burden resulting from the limitations on PRN orders for psychotropic drugs. These commenters said that the 14-day limitation could negatively impact the resident care. Many facilities, especially those that are small or in rural areas, already have difficulty with access to physicians and other health care providers, especially mental health practitioners. They were very concerned that there could be interruptions in resident care due to PRN orders expiring according to the § 483.45(e)(4) and (5) and not being renewed or getting another order before that time. To avoid not being in compliance with the requirements for PRN orders, some commenters were concerned that prescribers would write routine orders that would result in residents receiving more of the drug more often than if it were given PRN or only as needed.

We have also received feedback from both providers that primarily focused their comments on the burden imposed by the PRN requirements and advocates for residents that focused their comments on residents' rights. For example, a large organization representing mental health professionals indicated that they fully understood the need for safeguards to protect residents from inappropriate prescribing practices that place the convenience of the caregivers above the residents' interests. However, they also stated that the policies CMS had instituted on psychotropic drugs, were interfering with psychiatrists being able to appropriately treat residents with mental health and substance abuse disorders. They pointed to the increased scrutiny surrounding psychotropic medications, as well as the requirement for gradual dose reductions. They stated that the requirement for the in-person evaluation for residents who were on a PRN order for an anti-psychotic was unrealistic considering the access to care issues in several care settings. In addition, they were concerned about what they described as ''minimal standardized guidance provided to CMS surveyors'' that had resulted in ''improper rejections/citations for *appropriate* pharma-therapeutic decisions and documentation by psychiatrists, and this has become very detrimental to their patients'' while resulting in a significant administrative burden. This perspective demonstrates that while providers want to provide quality care to residents they can be frustrated with increased administrative burden and pressure to not use medications they believe are appropriate for the residents they care for.

Another perspective is evident in a report published on February 5, 2018, by the Human Rights Watch (HRW), ''They Want Docile''—How Nursing Homes in the United States Overmedicate People with Dementia'' (*https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia*).

This report describes their findings based on visiting numerous nursing homes, interviewing nursing home residents, their families, the facility staff, and other officials and experts in LTC care, including LTC ombudsmen, as well as an analysis of publically available data, including academic studies. This report found, among other things, that anti-psychotic medications were being used as chemical restraints and for the convenience of the staff in LTC facilities. Residents that were interviewed described how traumatic it was to lose their ability to stay awake, think, and communicate. The report also noted that a review of the data, as well the interviews, suggested that some nursing homes are circumventing the pressure to reduce anti-psychotic drug use by seeking an appropriate diagnosis from a physician that would justify the use of these drugs for a resident, typically schizophrenia. This concern was significant enough for numerous organizations to issue a joint statement on ''Diagnosing Schizophrenia in Skilled Nursing Centers.'' [1] that read, in part, ''[w]hile there is a national need for better and more approved treatments for behavioral and psychiatric symptoms in dementia, clinicians need to be mindful of, and avoid, labeling patients with other diagnoses to justify the use of medications or other treatments.''

In proposing changes to the PRN requirements for psychotropic medications, which include anti-psychotic drugs, we must ensure that the proposed requirements provide sufficient protections for residents from receiving inappropriate or unnecessary drugs and that medications are prescribed for residents based on their health care needs and not for the convenience of the staff or any other inappropriate reasons. However, we must also be mindful not to propose requirements that are overly burdensome to the facilities and health care providers that do not contribute to the quality of care for the residents, especially if they could result in interfering with residents receiving appropriate care for their health care needs.

Based on further consideration and the feedback we received, we agree that the current requirements could result in interruptions to some residents' care that could have a negative impact. Therefore, we propose to revise § 483.45(e)(4) and (5). Revised § 483.45(e)(4) would state that ''PRN orders for psychotropic drugs are limited to 14 days. If the attending physician or prescribing practitioner

[1] ''Joint Summary Statement—Diagnosing Schizophrenia in Skilled Nursing Centers,'' press release, The Society for Post-Acute and Long-Term Care Medicine, February 21, 2017, *http://www.paltc.org/newsroom/joint-summary-statement diagnosing-schizophrenia-skilled-nursing-centers* (accessed August 20, 2018).

believes that it is appropriate for the PRN order to be extended beyond 14 days, the order can be extended in accordance with the facility's policy if he or she documents his or her rationale in the resident's medical record and indicates the duration for the PRN order.'' Thus, there would be no distinction between anti-psychotics and other psychotropic medications. Section 483.45(e)(5) would be revised to require, in addition to the current requirements, that the facility's policies, standards, and procedures use recognized standards of practice; including the circumstances upon which PRN orders for psychotropic drugs could be extended beyond the 14-day limitation; and that the facility take into consideration individualized resident' needs for psychotropic drugs. We believe that having the same requirements for all psychotropic drugs will simplify the survey process and reduce improper deficiency citations, as well as remove potential obstacles for mental health professionals to provide quality care for residents. We believe that these changes will provide the flexibility that facilities and providers need to assure that they can care for their residents without excessive administrative burden.

We have not indicated any specific ''recognized standards of practice.'' We expect that experts in medicine and pharmacology would develop national standards that could be used in LTC facilities. In addition, we would be interested in any comments on standards that could be used to satisfy this requirement. We would also expect the mental health professionals that practice in the facility, as well as the medical director and director of nursing for the facility, would have significant input into the facilities' policies.

We remain concerned about the potential misuse of psychotropic drugs, especially anti-psychotics. Therefore, we are soliciting comments on whether these proposed modifications to the requirements concerning PRN orders for psychotropic drugs provide sufficient protection for residents. We welcome feedback on whether CMS should retain the current PRN policy for anti-psychotic drugs. We are also interested in additional information regarding the impact that the current PRN policy for anti-psychotic drugs has on resident care in LTC facilities, such as access to health care professionals, timing of a resident receiving necessary medications, interruptions in resident care, or any other consequences of retaining the current PRN policy for anti-psychotic drugs. In addition, we welcome feedback regarding alternative policy options that CMS could take to address concerns surroundings PRN orders of psychotropic drugs and an explanation of how such alternative policy options would provide resident protections, without limiting a resident's access to necessary medications. Furthermore, we are requesting feedback as to whether the 14-day limitation on PRN orders is reasonable, especially in light of the proposal to allow a prescriber to extend the order by writing his or her rationale in the resident's medical record and indicating the duration of the order. If not reasonable, we request that commenters provide recommendations to improve these proposed requirements. Lastly, we request feedback as to whether there should be a specific requirement for evaluating residents before renewing a PRN order for an anti-psychotic drug and if so, at what time intervals and what type of evaluation should be required?

7. Food and Nutrition Services (§ 483.60)

Dietary standards for residents of LTC facilities are critical to both quality of care and quality of life. The October 2016 final rule extensively revised the requirements related to food and nutrition services, including a burden reducing requirement that allows a resident's attending physician to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing a resident's diet to the extent allowed by state law. In addition, the October 2016 final rule established qualifications for a director of food and nutrition services when a dietitian is not employed by a facility full-time. Specifically, regulations at § 483.60(a)(2)(i) state that if a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services. Under the existing regulations, the director of food and nutrition services must be a certified dietary manager; a certified food service manager; have similar national certification for food service management and safety from a national certifying body; or have an associate's or higher degree in food service management or in hospitality (if the course study includes food service or restaurant management). Individuals designated as the director of food and nutrition services prior to November 28, 2016, have 5 years to obtain the specified credentials and an individual designated after November 28, 2016, have 1 year to obtain the specified credentials. Furthermore, § 483.60(a)(2)(ii) specifies that the director of food and nutrition services could satisfy this requirement if they have met applicable state requirements to be a food service manager or dietary manager.

LTC stakeholders have shared concerns regarding the requirement that existing staff become certified dietary managers or food service managers. Specifically, industry stakeholders have concerns regarding the need for existing dietary staff, who are experienced in the duties of a dietary manager and currently operate in the position, to now obtain new or additional training to become qualified under the requirements. We believe that effective management and oversight of the food and nutrition service is critical to the safety and well-being of all residents of a nursing facility. Therefore, we continue to believe that it is important that there are standards for the individuals who will lead this service. However, after further consideration of stakeholder feedback, we understand that the move from no established standards prior to the October 2016 final rule for a director of food and nutrition services, to the level of standards established in the October 2016 final rule, may have subjected facilities to unnecessary burden and increased costs. Furthermore, despite the timeframes built into the requirements for existing and newly hired staff to obtain the specified credentials, we understand that facilities are concerned about a workforce shortage of certified dietary managers and the financial costs imposed on existing experienced staff to obtain specialized training.

Therefore, we propose to revise the standards at § 483.60(a)(2) to increase flexibility, while providing that the director of food and nutrition services is an individual who has the appropriate competencies and skills necessary to oversee the functions of the food and nutrition services. Specifically, we propose to revise the standards at § 483.60(a)(2)(i) and (ii) to provide that at a minimum an individual designated as the director of food and nutrition services is one who has 2 or more years of experience in the position of a director of food and nutrition services or has completed a minimum course of study in food safety that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving. We are retaining the existing requirement at § 483.60(a)(2)(iii) which specifies that the director of food and nutrition services must receive frequently scheduled consultations from a

qualified dietitian or other clinically qualified nutrition professional. These proposed revisions would maintain established standards for the director of food and nutrition services given the critical aspects of their job function, while addressing concerns related to costs associated with training existing staff and the potential need to hire new staff.

8. Administration (§ 483.70)

The existing regulations at § 483.70(e) require each facility to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents during both day to-day operations and emergencies. The facility assessment requirement is intended to be used by the facility for multiple purposes, including, but not limited to, activities such as determining staffing requirements, establishing a QAPI program and conducting emergency preparedness planning.

Currently, the facility must review and update that assessment, as necessary, and at least annually. The facility must review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. LTC providers are to address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.

We have received feedback from the provider community and other stakeholders stating that the facility assessment requirements at § 483.70(e) are excessively burdensome because they require information collection similar, but not identical, to other information collections required by the regulations. They stated that these requirements are very detailed and that they micro-manage how SNF/NFs must operate their businesses. They also stated that complying with existing provisions requires an immense amount of administrative time and that this reduces valuable leadership time that can be used for resident care. After a careful review of the current requirements, we propose to reduce burden by removing unnecessary requirements and clarify that data collected under the facility assessment requirement can be utilized to inform policies and procedures for other LTC requirements. For example, the requirements for Nursing services (§ 483.35), Behavioral health services (§ 483.40(a)) and Food and nutrition services (§ 483.60(a)) would all be able to utilize data from the facility assessment. In addition, the current QAPI requirement at § 483.75(c) requires facilities to establish requirements for QAPI program feedback, data systems and monitoring. Facilities must maintain effective systems to obtain and use feedback and input from direct care/direct access workers, other staff, residents, resident representatives and families to identify opportunities for improvement. The data collected under the QAPI requirement could be used to meet portions of the facility assessment requirements and vice versa. Many of the health and safety requirements were developed to complement and support each other to ensure optimum health and safety for the beneficiaries. In addition, we have identified some of the LTC requirements that are duplicative of requirements for emergency preparedness. LTC facilities are required under § 483.73(a) to develop and maintain an emergency preparedness plan that must be based on a documented facility-based and community-based risk assessment, utilizing an all-hazards approach. The emergency preparedness requirements that were effective on November 15, 2016, under § 483.73(a) also require LTC facilities to conduct a facility and community-based risk assessment. The emergency preparedness requirements are very detailed and discuss the full range of requirements for a facility to have an emergency plan, conduct a risk assessment, have policies and procedures, a communication plan, and conduct training and testing. As such, we are proposing to remove the unnecessary requirement at § 483.70(e)(3) that requires each facility to conduct and document a facility-wide assessment for both day to-day operations and emergencies.

The requirements at § 483.70(e)(1) through (2) will remain. We are proposing to change the minimum frequency in which a facility should conduct a facility assessment under this requirement from an annual assessment to a biennial facility-wide assessment. We note that this does not preclude facilities from conducting an assessment more frequently than every 2 years. We believe that in facilities with a high staff turnover, assessments should take place as frequently as necessary and the issue should be addressed in the QAPI plan. Facilities must present their QAPI plan at each annual recertification survey and upon request during any other survey and to CMS upon request. The QAPI program must be ongoing, comprehensive, and address the full range of care and services provided by the facility and must present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the program requirements. Thus, we believe that the combined LTC requirements (for example, emergency preparedness; QAPI; and facility assessment) would help to optimize health and safety, while reducing burden. A facility would review and update its assessment as necessary, and, at a minimum, every 2 years. We believe that this would further reduce burden and improve administrative flexibility, especially for rural providers with limited resources.

9. Quality Assurance and Performance Improvement Program (§ 483.75)

Section 1128I of the Act, added by section 6102 of the Affordable Care Act, requires the Secretary to establish and implement a QAPI program for LTC facilities. LTC stakeholders have shared concerns with us regarding the prescriptiveness of the QAPI regulations implemented in the October 2016 final rule. Specifically, some industry stakeholders have indicated that they believe that the QAPI regulations are inflexible and too detailed, making it difficult for facilities to identify organizational priorities for improvement. However, resident advocates indicated that the QAPI process is new in the LTC setting and specificity in the requirements is necessary to ensure consistency and efficacy of the QAPI process.

After further consideration and a review of stakeholder feedback, we believe that the level of specificity and detail in the QAPI requirements, established in the October 2016 final rule, may limit a facility's ability to design their QAPI program to fit their individual needs and hinder a facility's QAPI program from being a valuable tool in promoting quality care. Therefore, we are proposing to revise the requirements to allow facilities more flexibility.

We note that we are not proposing to revise the existing language at § 483.75(a)(1) through (4). Section 483.75(a) requires each LTC facility, including a facility that is part of a multiunit chain, to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. Regulations at § 483.75(a)(1) through (4) specify that facilities must maintain documentation and demonstrate

evidence of its QAPI program; must present the initial QAPI plan to the State Survey Agency no later than 1 year following the promulgation of the October 2016 final rule (November 28, 2017); must present the QAPI plan at each annual recertification survey and upon request during any other survey and to CMS upon request, and lastly must present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the program requirements to a State Survey Agency, federal surveyor, or CMS upon request.

In response to the FY 2018 SNF PPS proposed rule comment solicitation, some commenters indicated that for a QAPI program to meet its true intent and be successful, QAPI-related documents should remain confidential in all surveys. Commenters indicated that they have concerns regarding how the QAPI documents will be used during facility surveys and one commenter noted that QAPI-based citations in recent surveys have been used as a ''gotcha'' citation instead of focusing on true quality outcomes. Commenters noted that requiring facilities to disclose their QAPI-related documents limits a facility's ability to identify and prioritize what they believe is important and instead requires them to monitor everything all the time.

We are retaining the existing requirements at § 483.75(a)(1) through (4) because we believe that these requirements are necessary for facilities to demonstrate compliance and to ensure that a facility's QAPI program is ongoing. As part of our certification and enforcement efforts, we have a responsibility to determine compliance through the use of evidence provided by facilities to support compliance decisions. Therefore, we note that to avoid the risk of facility noncompliance, facilities must be able to provide satisfactory evidence that demonstrates compliance with the requirements. Furthermore, we expect that any review of QAPI related documents would occur at the end of the survey, after completion of investigation into all other requirements to ensure that concerns are identified by the survey team independent of the QAPI document review. We encourage readers to refer to the interpretive guidelines for the October 2016 final rule for a full discussion regarding disclosure of information and good faith attempts (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf*).

We are proposing revisions to § 483.75(b), (c), and (d) that would remove the subparagraphs found in each section. Specifically, regulations at § 483.75(b) sets forth parameters for a facility's QAPI program design and scope. We propose to maintain only the introductory text at § 483.75(b), which requires that the QAPI program be ongoing, comprehensive, and address the full range of care and services provided by the facility, and to remove the detailed requirements at § 483.75(b)(1) through (4).

Regulations at § 483.75(c) set forth specific requirements for program feedback, data systems and monitoring. We propose to maintain only the introductory text at § 483.75(c), which requires that facilities establish and implement written policies and procedures for feedback, data collection systems, and monitoring, including adverse event monitoring, and remove the detailed requirements at § 483.75(c)(1) through (4).

Regulations at § 483.75(d) set forth specific requirements for program systematic analysis and systemic action. We propose to maintain § 483.75(d)(1), which requires facilities to take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained, and remove the detailed requirements for policies at § 483.75(d)(2).

We believe that these proposed revisions recognize the diversity throughout LTC facilities and would reduce burden on facilities by allowing facilities greater flexibility in tailoring their QAPI programs to the specific needs of the facility. In addition, the proposed requirements for the QAPI program would be consistent with the QAPI requirements for other Medicare and Medicaid participating providers, such as hospitals and other major inpatient provider types.

10. Infection Control (§ 483.80)

Section 483.80 requires LTC facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. Each facility must conduct an annual review of its IPCP and update its program, as necessary (§ 483.80(f)).

Currently, each facility must designate one or more individual(s) as infection preventionists (IPs) who are responsible for the facility's IPCP. The IP must—(1) have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field; (2) be qualified by education, training, experience or certification; (3) work at least part-time at the facility; and, (4) have completed specialized training in infection prevention and control. The IP must also be a member of the facility's quality assessment and assurance committee.

Some commenters expressed concern about the burden to providers in complying with these requirements, especially the requirements regarding the IPs. However, we received feedback about how important the new requirements are to improving infection prevention and control in LTC facilities. Infection is the leading cause of morbidity and mortality among the 1.7 million residents of United States nursing homes. Between 1.6 and 3.8 million infections occur each year in these nursing homes, with almost 388,000 deaths attributed to these infections. Significant costs are associated with infections in nursing homes, with estimates ranging from $673 million to $2 billion. An average of 15 percent of nursing homes from 2000 to 2007 received a deficiency citation regarding the infection control requirements (''Nursing home deficiency citations for infection control,'' Am J Infect Control. 2011 May; 39(4): 263–9). Most of these citations were at the D level, which means that they were isolated cases but represented a potential to do more than minimal harm. The infection prevention and control requirements must recognize the serious risks from infectious organisms in LTC facilities without imposing excessive administrative burden on these facilities that will not provide any commensurate improvement in the quality of care provided to residents. Based upon these facts and the feedback we have received regarding the importance of the infection prevention and control requirements in the LTC facility requirements, we believe that the requirements in the 2016 final rule should be retained. However, we are proposing one change to these requirements.

We believe it is essential that the facility's IP(s) have sufficient time to devote to the IPCP to ensure that he or she can achieve the objectives set forth in the facility's IPCP. As set forth in § 483.80(a)(1), the facility must use the facility assessment conducted according to § 483.70(e) in developing its IPCP. Thus, the time necessary for an IP to devote to the facility's IPCP will vary between facilities. Currently, § 483.80(B)(3) requires the IP to work at least part-time at the facility. Part-time could be interpreted in various ways

and could result in confusion. In addition, depending upon the facility's IPCP, IPs might need to devote only a few hours to the IPCP or it might take one or more IPs full-time. Therefore, we are proposing to remove the requirement that the IP work at the facility ''at least part-time'' and insert that the IP must have sufficient time at the facility to meet the objective's set forth in the facility's IPCP. We believe this is an appropriate standard. However, we are also concerned that there could be a substantial variance in how LTC facilities interpret this requirement. Therefore, we are soliciting comments on how should it be determined that the IP has sufficient time to devote to the IPCP to ensure that he or she can achieve the objectives set forth in the facility's IPCP. Please be specific.

11. Compliance and Ethics Program (§ 483.85)

Section 483.85(d)(1)—Additional required components for operating organizations with five or more facilities; 483.85(e)—Annual review; Compliance and ethics—§ 483.95(f)(2).

Section 1128I of the Act requires the operating organizations for SNFs and NFs to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care consistent with regulations developed by the Secretary. In the final rule published on October 4, 2016, we finalized this requirement along with additional training and personnel requirement that were not expressly required in the statute. However, after a review of these requirements, we are proposing to reduce a majority of the burden currently required under the compliance and ethics program that are not required in the statute because we believe that the SNF and NF CoPs would have the appropriate safety and quality standards to support the compliance and ethics requirements with the proposed changes. Thus we propose to remove the following requirements:

- We propose to remove the requirement that each facility designate a compliance officer and a designated compliance liaison for operating organizations with five or more facilities. Instead, we would propose that such organizations develop a compliance and ethics program that is appropriate for the complexity of the organization and its facilities and that each facility assign a specific individual within the high-level personnel of the operating organization with the overall responsibility to oversee compliance.
- Based on feedback from the industry and stakeholders that the frequency requirement is overly burdensome, we propose to remove the annual review requirement and propose that each organization undertake a periodic assessment of its compliance program to identify any necessary changes. This proposed change would conform to the statutory requirement.
- We propose to eliminate the requirement for a ''compliance and ethics program contact person'' to which individuals may report suspected violations. However, we maintain that is important for individuals to report suspected violations, we will not specify the staff person for this task. Facilities must have a process to accomplish this and we don't want to dictate who they should hire to comply with this requirement. We will maintain the requirement that facilities should have an alternate method of reporting suspected violations anonymously. We would expect the facility to have sufficient resources and designate an individual that would have the appropriate authority to assure compliance with the requirements.
- We propose that the operating organization for each facility develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, established written compliance and ethics standards, policies, and procedures that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act.

We also propose that specific high-level personnel of the operating organization be assigned the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures. We propose to remove the statement in the regulation at § 483.85(c)(2) that states ''such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization could be assigned to oversee compliance.'' We are proposing to remove this prescriptive language and would, instead, hold facilities responsible for the effective operation of its program. For additional guidance, we note that the Department of Health and Human Services' Office of the Inspector General (OIG) has issued industry-specific guidance documents in the March 16, 2000 **Federal Register** (65 FR 14289) entitled ''Publication Of The OIG Compliance Program Guidance For Nursing Facilities'', and in the September 30, 2008 **Federal Register** (73 FR 56832) ''OIG Supplemental Compliance Program Guidance For Nursing Facilities.'' The guidance reiterates the basic elements of a compliance and ethics program. It should be the responsibility of the facility to designate an appropriate person to be responsible for all aspects of the compliance and ethics program.

We would expect that the facility would give designated individuals sufficient resources and authority to reasonably assure compliance with the program's standards, policies, and procedures. The facility should not delegate substantial discretionary authority to individuals whom the operating organization knows (or should have known through the exercise of due diligence) had a propensity to engage in criminal, civil, and administrative violations under the Act.

We propose that the facility effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements would include, but are not limited to, mandatory participation in training as set forth in § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program. Also, the facility should take reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps would include, but not be limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others within the operating organization without fear of retribution.

The compliance and ethics program contact identified in the operating organization's compliance and ethics program would be required to ensure consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation.

After a violation is detected, the operating organization would have to ensure that all reasonable steps

identified in its program were taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

In addition to the listed requirements, operating organizations that operate five or more facilities and facilities with corporate level management of multi-unit nursing home chains would have to:

- Have a more formal program that included established written policies defining the standards and procedures to be followed by its employees.
- Develop a compliance and ethics program that was appropriate for the complexity of the operating organization and its facilities.

We are proposing to revise § 483.85(e) to require the operating organization for each facility to periodically review and revise its compliance program to identify necessary changes within the organization and its facilities.

12. Physical Environment (§ 483.90)

a. Life Safety Code

On May 4, 2016, we published a final rule, ''Medicare and Medicaid; Fire Safety Requirements for Certain Health Care Facilities,'' adopting the 2012 edition of the National Fire Protection Association (NFPA) 101 (81 FR 26871), also known as the Life Safety Code (LSC). One of the mandatory references in the LSC is NFPA 101A, Guide on Alternative Approaches to Life Safety, also known as the Fire Safety Equivalency System (FSES). On December 16, 2016, CMS issued a survey & certification memo (S & C 17–15–LSC) updating to the newer edition of the NFPA 101A FSES. However, when we updated to the newer FSES that is part of the recently adopted 2012 LSC, some LTC facilities that utilized the FSES in order to determine compliance with the containment, extinguishment and people movement requirements of the LSC were no longer able to achieve a passing score, on the FSES, because of the change in scoring. When adopting the 2012 edition of the LSC and its FSES scoring values we did not anticipate this outcome. Additionally, during the public comment period for the proposed rule (79 FR 21551) we did not receive any public comments to indicate that this would be problematic for certain LTC facilities. Some existing LTC facilities were previously built with wood frame or unprotected steel construction with less than 2 hours of fire rated protection and are 3 or more stories in height. These facilities are fully sprinklered in order to meet both the LTC regulations at § 483.90(a)(6), and the LSC requirements. However, in order to score high enough to meet the FSES standards that are part of the 2012 edition of the LSC, these particular facilities would have to improve their construction type to one that is at least 2 hours of fire rated protection. Changing the construction type from being less than 2 hours of fire rated protection to being at least 2 hours of fire rated protection is extremely burdensome because such construction would completely disrupt the operation of the facility for a substantial period of time. In addition to the quality of care impacts and the financial impacts of service disruptions upon affected facilities in the form of lost revenues of such service disruptions, the significant cost of completing such construction, which we estimate to be $4.75 million per typical affected LTC facility, is likely to result in some permanent facility closures. We believe this would create access to care problems for affected residents and their surrounding communities, in addition to financial hardships for facility owners and staff. In light of the fact that we were not aware of this problem ahead of time, we did not allow for a regulatory phase-in period. However, the S & C 17–15–LSC memo from December 16, 2016 does allow for facilities to have immediate relief by applying for a time-limited waiver of up to 5 years while we pursue a long-term solution. We believe that there is a need for regulatory relief.

In order to address this need, we propose to allow those existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment and people movement requirements. Allowing the use of the 2001 FSES scoring values would continue to provide the same amount of safety for residents and staff as has been provided since we began implementing the 2001 FSES in 2003. This would allow existing LTC facilities that previously met the FSES requirements to continue to do so without incurring great expense to change construction type. Based on a review by the states and regional offices, we estimate that there are 50 existing LTC facilities that would no longer be able to achieve a passing score on the new FSES requirements. This is an estimate based on feedback from facilities, states, and CMS Regional Offices. We are proposing to use the following mandatory scoring values:

Table 1. Proposed Mandatory Values—Nursing Homes

	Containment (Sa)		Extinguishment (Sb)		People Movement (Sc)	
Zone Location	New	Exist.	New	Exist.	New	Exist.
1st story	11	5	**15(12)***	4	**8(5)***	1
2nd or 3rd story **	15	9	**17(14)***	6	**10(7)***	3
4th story or higher	18	9	**19(16)***	6	**11(8)***	3

* Use ( ) in zones that do not contain patient sleeping rooms.

We would set out this table at § 483.90(a)(1)(iii).

b. Resident Rooms and Bathrooms

The physical environment of a nursing facility is integral to the resident's health and safety. Therefore, the facility must be designed, constructed, equipped, and maintained to protect the health and safety of

residents, personnel, and the public. The October 2016 final rule implemented new physical environment requirements at § 483.90 related to space and accommodations within facilities. Specifically, regulations at § 483.90(e)(1)(i) require newly constructed, re-constructed, or facilities first certified after November 28, 2016 (the effective of Phase One of the October 2016 final rule) to accommodate no more than two residents in a bedroom. Regulations at § 483.90(f) require newly constructed and facilities first certified after November 28, 2016 to equip each resident room with its own bathroom that has a commode and sink.

The October 2016 final rule responded to commenters' concerns that the proposed rule was too burdensome; however, industry stakeholders have continued to share concerns regarding the burden associated with these requirements, specifically noting that the requirements discourage building, remodeling, upgrading, and the purchasing of facilities. We recognize these concerns and unintended consequences. However, we continue to believe that the finalized physical environment requirements address valid health and safety concerns. Specifically, we believe that more than two residents to a room not only infringes on a resident's privacy and dignity, but also creates issues related to infection control and resident safety. Likewise, we believe that rooms without bathrooms increase risks related to falls, quality of care, and infection control.

Therefore, we are not proposing to entirely remove these requirements. We are proposing to revise § 483.90(e)(1)(i) regarding the number of residents per room and § 483.90(f) regarding bathroom facilities, to apply only to newly constructed facilities and newly certified facilities that have never previously been a long-term care facility. We believe that these revisions would reduce burden by removing any unintended disincentives to purchase or upgrade existing facilities, while ensuring that any new facilities (either newly constructed or converted into a nursing home) are properly equipped to accommodate residents in a reasonable and safe manner. However, we note that when purchasing or updating facilities, this may create an opportune time to update facility rooms and bathrooms in an effort to address infection risks and quality of life concerns. For example, when providing care for residents during a norovirus outbreak, having sinks in resident rooms would allow staff easier access to wash their hands and conduct effective infection prevention and control practices to avoid further contamination. Therefore, we are soliciting comments as to whether it would be appropriate to sunset the exception we propose to provide for buildings that were previously long-term care facilities. If so, what would be a reasonable time frame for sunsetting this exemption to balance the needs of residents for privacy, quality of life, and infection prevention and the desire to maintain access to facilities and avoid the unintended consequences discussed previously.

13. Technical Corrections

Admission, Transfer, and Discharge Rights § 483.15

Section 483.15 includes an incorrect cross-reference. Specifically, § 483.15(c)(1)(ii) includes an incorrect cross-reference to § 431.220(a)(3). We propose to revise § 483.15(c)(1)(ii) to correct the cross reference by replacing ''§ 431.220(a)(3)'' with ''§ 431.220(a)(2)''.

Nursing Services § 483.35

Section 483.35 includes incorrect cross-references. Specifically, § 483.35(a)(2) and § 483.35(e)(4) include incorrect cross-references to paragraph (c) of this section. In addition, § 483.35(f)(2) includes an incorrect cross-reference to paragraph (d)(1) of this section. We propose to revise § 483.35 to correct the cross references by replacing ''paragraph (c)'' with ''paragraph (e)'' in § 483.35(a)(2) and (e)(4) and replacing ''paragraph (d)(1)'' with ''paragraph (f)(1)'' in § 483.35(f)(2).

Physical Environment § 483.90(d)

On July 13, 2017, we issued a correcting amendment, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (82 FR 32256) to correct technical and typographical errors identified in the October 4, 2016 final rule. This document inadvertently removed revisions made to § 483.90(d), which were finalized in the October 2016 final rule. Specifically, the October 2016 rule finalized requirements at § 483.90(d) (incorrectly labeled paragraph (c) in the October 2016 final rule) for facilities to—(1) provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care at § 483.90(d)(1)); (2) maintain all mechanical, electrical, and patient care equipment in safe operating condition at § 483.90(d)(2); and (3) conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible at § 483.90(d)(3).

We discussed the revisions in § 483.90(d) in the October 2016 final rule, responded to public comments related to this issue, and concluded that we were finalizing the requirement (see 81 FR 68817). Therefore, we are proposing to correct the error in the Code of Federal Register to revise § 483.90(d)(1) and to add § 483.90(d)(3).

Diagnostic X Ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Condition (§ 410.32)

Section 410.32 includes an incorrect cross-reference to Part 483. Specifically, § 410.32(d)(1)(vii) includes an incorrect cross-reference to § 483.75(k)(1)(i). We propose to revise § 410.32(d)(1)(vii) to correct the cross reference by replacing ''§ 483.75(k)(1)(i)'' with ''§ 483.50(a)(1)(i)''.

B. Survey, Certification, and Enforcement Procedures

1. Informal Dispute Resolution (IDR) (§ 488.331) and Independent Informal Dispute Resolution (§ 488.431)

To assess compliance with the LTC requirements, surveyors conduct onsite inspections (surveys) of facilities. In the survey process, surveyors directly observe the actual provision of care and services to residents and the effect or possible effects of that care to assess whether the care provided meets the assessed needs of individual residents.

Among the statutory enforcement remedies available to the Secretary and the states to address facility noncompliance are CMPs, authorized by sections 1819(h) and 1919(h) of the Act. CMPs may be imposed for each day or each instance of facility noncompliance, as well as for past instances of noncompliance even if a facility is in compliance at the time of the current survey. The regulations that govern the enforcement remedies authorized by the statute, were published in the **Federal Register** on November 10, 1994 (59 FR 56116).

Facilities that are dissatisfied with a certification of noncompliance have an informal opportunity, if they request it, to dispute cited deficiencies upon receipt of the official statement of deficiencies. For surveys conducted pursuant to section 1864 of the Act, this informal dispute resolution (IDR)

process is provided by the state. The requirement for IDR is specified at § 488.331. Policy guidance in section 7212 of CMS's *State Operations Manual* (Pub. 100–07) (SOM) specifies the mandatory elements that must be included in each State's IDR process. There is no specification for how long the IDR process should take to be completed. We are proposing to add language to specify that IDR would be completed within 60 days of the facility's request to dispute the survey findings if the request by the facility is timely. This is consistent with the time frame for the completion of an Independent IDR.

NFs and dually-participating SNF/NFs are provided the opportunity to request and participate in an Independent IDR if CMS imposes CMPs against the facility. The requirement for Independent IDR is specified at § 488.331. Policy guidance in section 7213 of CMS's SOM specifies the mandatory elements that must be included in each State's Independent IDR process. Current guidance in the SOM at 7212.3 and 7213.9 specify that the results of a survey should not be uploaded to the Certification and Survey Provider Enhanced Reports (CASPER) system before the resolution of the IDR or the Independent IDR. We are proposing to add this language in regulation as we have been made aware that these instructions are not always being followed; and entering the survey results before the dispute processes have been completed may negatively affect a facility's Five Star quality rating on Nursing Home Compare.

Current guidance in the SOM at 7213.6 specifies the qualifications of an approved Independent IDR reviewer (entity or person). One of the qualifications is a specific understanding of Medicare and Medicaid program requirements. While this is specified in regulation regarding an independent entity, it is not specified in the example given of a component of an umbrella State agency that is separate from the SA. In order to clarify that this is indeed a requirement for the component, we are proposing to add language to the regulation.

Note: State health agencies are either independent agencies or a unit of a larger agency, often referred to as an umbrella agency.

Finally, as outlined in current sub-regulatory guidance when an outside entity conducts the Independent IDR process based on the results of a state-conducted or federally-conducted survey, the results serve only as a recommendation of noncompliance or compliance to the State or CMS. If the State or CMS disagrees with the Independent IDR recommendation, the written record provided to the facility will contain the result of each deficiency challenged and a summary of the rationale for that result so that the facility understands the Independent IDR panel's recommendation and why the State or CMS do not agree with that recommendation.

Current SOM guidance provides instruction regarding what should be provided to the facilities as part of the written record but CMS has been made aware that the facility is sometimes only receiving the final decision and no rationale is included for the decision, which leads to confusion as to why an Independent IDR recommendation is not followed. We are proposing to add this language in regulation to strengthen this requirement.

Based on stakeholder input, we propose that additional language be added to the CMS enforcement regulations at § 488.331 and § 488.431 to clarify and strengthen regulations and provide more specific requirements to states and CMS regarding both the IDR process and the Independent IDR processes. We would—(1) specify that an IDR process must be completed within the same timeframe that we specify for the Independent IDR process; (2) provide states with more specific instructions on when the results of a survey should be transferred for inclusion in the national reporting system; (3) clarify the knowledge required by an approved independent entity; and (4) specify that the final result of an Independent IDR (including the rationale behind the decision) must be relayed to a facility by either the state or CMS in writing. We discuss these proposed revisions and invite public comment on the proposed changes.

We proposed to revise § 488.331(b)(1) by adding new language to specify that the IDR process shall be completed within 60 days of the facility's request to dispute the survey findings if the request by the facility is timely. In order to reduce confusion and ensure consistency between the IDR and Independent IDR processes, we are requiring the same time frame for completion for both processes. In the case where a CMP is imposed, facilities disputing the survey results are still required to pay the CMP and it is held in an escrow account until a final administrative decision has been made. Specifying the time frame for the completion of the IDR process will potentially reduce burden on facilities who will have the money returned to them sooner when they are successful in their appeal.

At proposed § 488.331(b)(2), we propose to add specific instructions to states explaining when survey results should be uploaded into the CASPER system. These survey results are used to calculate a facility's Five-Star quality rating on the Nursing Home Compare website and are not to be uploaded into CASPER before the resolution of the IDR or Independent IDR processes. This specification will provide consistency to the upload process and prevent survey results from being uploaded prior to completion of the dispute process. Recognizing that the public as well as other organizations, use Nursing Home Compare to assist in decision-making about residing or contracting with a specific facility, this will reduce burden on providers by ensuring that the CMS website contains accurate survey information that includes any post-survey review through the IDR or Independent IDR process. It would also reduce burden on states by minimizing the amount of corrections and changes to data that would need to be made if information were uploaded prematurely.

At § 488.431(a)(2), we propose to add new language to specify that the facility must receive written notification of the results of the Independent IDR, including the rationale for the final decision. The rationale must be provided by CMS or the states depending upon who made the final determination. Although SOM guidance instructs states and CMS to send written notification of the Independent IDR recommendation to the facility, there may be times when the state or CMS disagrees with the Independent IDR entity's recommendation and it is not accepted as the final decision. In this case, the rationale for the disagreement must be documented by CMS or the state as part of their normal process and provided to the facility to ensure clarity in why a final decision was made that differs from the Independent IDR's recommendation. This would reduce burden on facilities as, adding this to regulation, they would be made aware of the availability of this information and would not have to spend time trying to figure out the process for requesting an explanation of the final decision.

At § 488.431(a)(4)(i), we propose to add language to clarify that, in order to be approved to conduct an Independent IDR, a component of an umbrella state agency must have a specific understanding of Medicare and Medicaid program requirements. Although this information is provided in guidance, including it in regulation will strengthen this provision. In

addition, it will reduce burden by decreasing the possibility of providers having to dispute the qualifications of the entity chosen to conduct the Independent IDR process and/or its recommendations.

2. Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

Requirements at § 488.436 regarding the option for a facility to waive hearing rights and receive a 35 percent reduction in the amount of CMPs owed were first adopted in a 1994 final rule (59 FR 56116–01), with minor corrections to the text in 1997 (62 FR 44221). Over the years, we have observed that most facilities facing CMPs do not request a hearing to appeal the survey findings of noncompliance on which their CMPs are based. In CY 2016, 81 percent of LTC facilities submitted a written waiver of the hearing and an additional 15 percent of facilities failed to submit a waiver although they did not contest the penalty and its basis. Only 4 percent of facilities availed themselves of the full hearing process. Therefore, based on our experience with LTC facilities facing CMPs and the input provided by CMS Regional Offices who impose and collect CMPs, we propose to revise these requirements at § 488.436 by creating a constructive waiver process that would produce the same, or better, results for less money and effort.

Specifically, we propose to revise the current express waiver process to one that seamlessly flows to a constructive waiver and retains the accompanying 35 percent penalty reduction. This would result in lower costs for most LTC facilities facing CMPs and would streamline and reduce the administrative burden for all stakeholders.

We propose to amend the language at § 488.436(a), by eliminating the requirement to file a written waiver and create in its place a constructive waiver process that would operate by default when CMS has not received a timely request for a hearing. Facilities that wish to request a hearing would continue to follow all other appeals process requirements, including those at § 498.40, as currently referenced in part 488 at § 488.431(d).

We propose language at § 488.436(a) stating that a facility is deemed to have waived its rights to a hearing if the time period for requesting a hearing has expired and CMS has not received a timely request for a hearing. For the 81 percent of LTC facilities that submit a written hearing waiver and receive a 35 percent reduction in the amount of their CMPs, these facilities must then pay the amount due (minus the 35 percent reduction). We have observed that many facilities submitting a request for a waiver of hearing wait until close to the end of the 60-day timeframe within which a waiver must be submitted, thus delaying the ultimate due date of the CMP amount. For these reasons, we believe the constructive waiver process would meet the needs of most facilities facing CMPs.

We believe that other circumstances can be addressed under § 488.444, whereby CMS has authority to settle CMP cases at any time prior to a final administrative decision for Medicare-only SNFs, state-operated facilities, or other facilities for which CMS' enforcement action prevails, in accordance with § 488.30. We believe that eliminating the current requirements at § 488.436 for a written waiver will not negatively impact facilities, and as such, we especially welcome comments from the public addressing any potential circumstances in which facilities' needs could best be met or only be met by the use of an express, written waiver.

In addition to the changes to § 488.436(a), we propose corresponding changes to § 488.432 and § 488.442 which now reference only the written waiver process. Finally, we note that the current requirements at § 488.436(b) would remain unchanged.

3. Phase 3 Implementation of Overlapping Regulatory Provision

The revised LTC requirements for participation are being implemented in three phases. Phases 1 and 2 were implemented in November of 2016 and 2017 respectively. Phase 3 includes additional regulatory provisions that are scheduled to be implemented on November 28, 2019. Each phase requires a significant level of activities, including interpretive guidance drafting and publication, provider education, software development, and surveyor training.

Of the Phase 3 provisions, this regulation proposes revisions that, if finalized, would have an impact on provisions that fall into three primary areas—(1) designation and training of the infection preventionist (§ 483.80), Quality Assurance and Performance Improvement (QAPI) (§ 483.75), and compliance and ethics program (§ 483.85). We list the specific regulatory citations in table 2 that follows.

Table 2. Impacted Phase 3 Regulatory Provisions

Current CFR Citation	Subject
483.75(a)(1), (4),	Quality Assurance and Performance Improvement
(b)(1)-(4)	Program Design and Scope
(c)(1)-(4),	Program Feedback, Data Systems, and Monitoring
(d)(1)-(2),	Program Systematic Analysis and Systematic Action
(e)(1)-(3),	Program Activities
(f)(1)-(6), and	Governance and Leadership
(g)(1)(iv), (g) (2)(iii)	Quality Assessment and Assurance
483.80(b)(1)-(4),(c)	Infection Preventionist Qualifications/Specialized Training
483.85(a)-(e)	Compliance and Ethics Program
483.95(d)	QAPI Training
483.95(f)(1)(2)	Compliance and Ethics Training

We are proposing to delay implementation of the above regulatory sections except for the requirements related to the Infection Preventionist at § 483.80(b)(1) through (4) and (c) and § 483.75(g)(1)(iv) (participation of Infection Preventionist on the quality assessment and assurance committee). We do not propose to delay the implementation of the infection preventionist requirements because the reduction in burden is related to the time required onsite. The requirements related to the infection preventionist's required training and role remain unchanged, and we therefore believe this requirement can be implemented as scheduled. For those requirements that we propose to delay implementation, we propose to implement them one year after the effective date of the finalization of this rule.

The purpose of this delay is to avoid unnecessary work, confusion and burden associated with implementing provisions that are proposed to be changed in this rule. We understand potential concerns regarding further delaying the implementation of the QAPI and compliance and ethics requirements, as these provisions were required to be implemented by statute in 2012 and 2013 respectively. However, we believe that moving forward with implementing these provisions in November 2019, only to implement significant revisions to the provisions proposed in this rule, would create significant additional work and confusion for the nursing home community. In addition, this would create administrative burden to Regions and States in software changes and surveyor re-training.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In analyzing information collection costs, we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2017 National Occupational Employment and Wage Estimates, United States by the Bureau

of Labor Statistics (BLS) at *https://www.bls.gov/oes/current/oes_nat.htm.* Furthermore, where applicable, the wage information for each occupation were pulled from the BLS industry category ''nursing care facilities (skilled nursing facilities). Based on this information, we have calculated the estimated hourly rates in this proposed rule based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation to these overhead and fringe benefit costs.

The table that follows presents the BLS occupation code and title, the associated LTC facility staff position in this regulation, the estimated average hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits and overhead costs).

Table 3. Summary Information of Estimated Hourly Cost

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1141	Registered Nurses	Registered Nurse	$31.59	$63
29-2061	Licensed Practical or Vocational Nurse	Licensed Nurse	$22.61	$45
11-9111	Medical and Health Services Managers	Director of Nursing	$44.59	$89
11-9111	Medical and Health Services Managers	Administrator	$44.59	$89
21-1022	Healthcare Social Workers	Social Worker	$24.48	$48
43-9061	Office Clerks, General	Office Assistant	$15.71	$31
29-1062	Family and General Practitioners	Physician	$95.54	$191
23-1011	Lawyer	Attorney	$68.22	$136
31-1014	Nursing Assistant	Nurse Aide	$13.20	$26
11-9051	Food Service Manager	Director of Food and Nutrition Services	$29.97	$60
29-1031	Dietitian	Dietitian	$27.98	$56
37-1010	First-line Supervisor of Building and Grounds and Maintenance Worker	Facility Manager	$19.24	$38

This proposed rule does not impose any new information collection, recordkeeping or third-party disclosure requirements. However, this proposed rule would create certain savings related to information collection, recordkeeping or third-party disclosure requirements. While we detail all of the estimated savings of this proposed rule in the regulatory impact analysis, this section provides a brief summary of the estimated savings associated with the information collection request (ICR) for LTC requirements (0938–1363) which will be sent to OMB for review. We are soliciting public comment on each of these issues for the following sections of this document that contain ICRs.

Requirements for Participation

1. ICRs Regarding Resident Rights (§ 483.10)

We propose several revisions to the regulations at § 483.10(j) that require facilities to develop a grievance policy. Proposed revisions include removing duplicative requirements, clarifying that everyday feedback may not rise to the level of an official grievance, removing

the requirement for facilities to designate a grievance official, remove prescriptive requirements related to written grievance decisions, and reducing the requirement for facilities to retain evidence demonstrating the results of grievances from 3 years to 18 months. Based on these proposals, we believe that there may be minor information collection cost reductions for developing a grievance policy. However, we believe that the majority of the cost savings are included in the proposal to remove the requirement for the grievance official to oversee the grievance process. We discuss these cost savings in the Regulatory Impact Analysis section.

2. ICRs Regarding Freedom, Abuse, Neglect, and Exploitation (§ 483.12)

The proposed revisions to the reporting requirements for abuse provide flexibility around the timeframes for reporting, but do not eliminate any of the reporting requirements. Therefore, while we believe the proposed revisions address stakeholder concerns and provide flexibility, the proposed revisions will have negligible effects on information collection costs.

3. ICRs Regarding Admission, Transfer, and Discharge Rights (§ 483.15)

We propose to revise the requirement for facilities to send copies of transfer or discharge notices to the Office of the State Long-Term Care Ombudsman to apply specifically to involuntary transfers or discharges only. In the October 2016 final rule we indicated that this cost would apply primarily to residents who are involuntarily discharged from the facility and does not include residents who request the transfer or who are transferred on an emergency basis to an acute care facility. Based on these assumptions, we estimated that the requirement would apply to one third of all LTC facility residents resulting in a cost of $1,340,936 related to make a copy of the notice, apply postage (if mailed), and the time of an office assistant to prepare and send the notice.

The proposed revisions would clearly establish the expectation that this requirement would apply to involuntary transfers or discharges only. Based on stakeholder comments, while we previously estimated that the requirement would apply to only one third of all LTC residents, many facilities have been sending the notice with all discharges and transfers rather than only involuntary discharges and transfers. Therefore, we estimate that the existing requirement applies to two thirds of all residents resulting in an updated estimated cost of $2,946,095 ($.10 (cost to make a copy per notice) + $.63 (cost for pre-stamped envelope based on USPS retail) + $2.58 (5/60 of an office assistant $31 hourly wage) × 889,163 (⅔ of 1,333,745 LTC residents)). We estimate further that with the proposed revisions, this requirement would apply to one third of all LTC facility residents, resulting in an estimated cost of $1,473,047 ($.10 (cost to make a copy per notice) + $.63 (cost for pre-stamped envelope based on USPS retail) + $2.58 (5/60 of an office assistant $31 hourly wage) × 444,582 (⅓ of 1,333,745 LTC residents)). Therefore, the cost savings to facilities would be the difference between sending notices related to all transfers and discharges versus involuntary transfers and discharges only, resulting in a total cost savings of $1,473,047 ($2,946,095 − $1,473,047).

4. ICRs Regarding Nursing Services (§ 483.35)

The proposed revisions in this section are related to record retention. While we believe that reducing the timeframe for maintaining records will produce cost savings to facilities, there are no collection of information requirements associated with this proposed change because maintaining records in this instance is considered a usual and customary practice in accordance with the implementing of regulations of the PRA 5 CFR 1320.3(b)(2).

5. ICRs Regarding Administration (§ 483.70(e))

LTC facilities are required to address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects) and equipment. We estimate that it takes a facility 20 hours annually to conduct and document a facility-wide assessment. As stated previously, the facility must utilize information collected under the requirements stated under this section and the information collection required under §§ 483.35, 483.40(a), 483.60(a), and 483.75. We estimate that it requires an administrator 8 hours to collect and analyze data from throughout the facility; 6 hours for the director of nursing to collect and analyze staffing data; 2 hours for an office assistant to collect and document data; and 2 hours each for a facility manager and a physician to review and provide input. We are proposing to reduce burden on facilities by changing the annual facility assessment requirement to a biennial requirement. We estimate that the burden would be reduced as follows: An administrator, at the hourly wage of $89 an hour × 8 = $712; director of nursing wage of $89 an hour × 6 hours = $534; office assistant wage of $31 an hour × 2 hours = $62; physician $191 an hour × 2 = $382; facility manager $38 an hour × 2 = $76. The total cost per facility is $1,766. We estimate a total burden reduction of 20 hours and $27.6 million in a 2-year period (15,639 SNFs/NFs × $1,770 per facility = $27,618,474). Since this savings occurs biennially, the annual savings is one-half of this, or $13,809,237.

6. ICRs Regarding Quality Assurance and Performance Improvement Program (§ 483.75)

Regulations at § 483.75 require facilities to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program. The existing information collection assumes that it would take appropriately 56 burden hours for a facility to develop and document a QAPI program designed to monitor and evaluate performance of all services and programs of the facility. We maintain this assumption. Based on 2017 BLS data, the estimated cost to comply with the QAPI requirements is $5,016 per facility (the facility administrator (30 hours × $89 = $2,670); the director of nursing (10 hours × $89 = $890); a registered nurse (10 hours × $63 = $630); a physician (4 hours × $191 = $764); and an office assistant (2 hours × $31 = $62). The total cost for 15,639 LTC facilities is an estimated $78,445,224.

This rule proposes to revise the requirements in § 483.75 to provide facilities with the flexibility needed to tailor their QAPI programs to the individual needs of their specific facility. Specifically, we have proposed to remove the prescriptive requirements at § 483.75(b)(1) through (4), and § 483.75(c)(1) through (4), and all of the requirements in § 483.75(d)(2). A detailed discussion of the proposed removal of these requirements can be found in section II.A.

The proposed removal of these prescriptive requirements would focus the QAPI requirements on the expected results of the program and would no longer prescribe the structures and methods for implementing the QAPI program. This provides flexibility to the facility, as it is free to develop a creative program that meets the needs of the facility and reflects the scope of its services and operations. Given the flexibility provided by the revisions and the variability across facilities as to where they are in the current efforts for developing a QAPI program, we believe

the expected savings that these flexibilities would provide to each individual facility is difficult to predict. However, we do expect that the added flexibilities would result in a reduction of the burden hours necessary to comply with these requirements.

Therefore, we assume that the current time and effort necessary to develop initial internal policies that reflect the individual goals set by the facility of 56 burden hours could be reduced by half. This would result in a cost of $2,508 per facility (the facility administrator (15 hours × $89 = $1,335); the director of nursing (5 hours × $89 = $445); a registered nurse (5 hours × $63 = $315); a physician (2 hours × $191 = $382); and an office assistant (1 hours × $31 = $31). The total cost for 15,639 LTC facilities is an estimated $39,222,612. Therefore, this would result in a burden reduction of 28 hours and $39,222,612 from the current requirement. This is a reduction in total burden hours of 437,892 (875,784 − 437,892). For purposes of this estimate, we assume that facilities have not incurred the full one-time cost to meet the existing requirement for initial policy development (due to be implemented November 2019), and that the amended requirement will not affect the annual implementation costs. We solicit public comment on our assumptions, and whether commenters believe there could be additional costs or savings that we have not included in this estimate, as well as on the accuracy of our savings estimate.

7. ICRs Regarding Compliance and Ethics Program (§ 483.85)

We propose to reduce burden by removing the mandatory annual training requirements for the operating organization's compliance and ethics program. We have proposed that each facility must review its compliance and ethics program biennially and revise its program as needed to within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care. In addition, we propose to change the annual review requirement to require operating organizations for each facility to review its compliance and ethics program biennially and revise its program as needed to reflect any changes.

For the purpose of this analysis, we are utilizing the burden rationale that we provided and published in the rule on October 4, 2016 (81 FR 68842). We have made cost updates to reflect current staff costs and number of facilities. We propose to reduce burden on facilities by eliminating the annual training requirement. There are currently about 15,639 SNFs and NFs. We estimate that training staff requires the duties of a RN for 2 hours per facility. The cost for all 15,639 facilities would be $1,970,514 (15,639 × 2 hours × $63 average hourly wage). This is a reduction of 31,278 burden hours. Based on our experience with SNF and NF facilities, we expect that operating organizations that operate 1–5 facilities have been able to minimize training costs by including the training on their compliance and ethics program with any current trainings or in-services that they already conduct for their staff.

Without data to make this assertion, we have made the above calculation apply to all facilities and ask for both data and comments regarding the savings associated with removing this requirement. Facilities would still be required to effectively communicate standards, policies and procedures through a training program or in another practical manner. For example, online or video training modules could be used. However, we are no longer designating the manner nor the frequency for such instruction, nor requiring that facility staff be trained to provide such instruction.

We also propose to reduce burden for § 483.85(e) by changing from an annual review to a biennial review of the compliance an ethics program. We expect that the administrator and director of nursing would annually spend 5 hours each reviewing the program to ensure its compliance. The administrator and director of nursing salaries would total $890 ($178 combined hourly total for the administrator and director of nursing × 5 hours). We estimate a biennial savings of $5,873,110 ($890 × 6,599 operating facilities) and 65,990 hours (6,599 operating facilities × 10 hours). Since this savings occurs biennially, the annual saving is one-half of this, or $2,936,555 and 32,995 hours

The total annualized reduction in information collection cost for these reforms would be an estimated $4,907,069 ($1,970,514 + $2,936,555). The total reduction in burden hours is 64,273 hours.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by September 16, 2019.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

We periodically review the Medicare and Medicaid health and safety standards in an effort to ensure that they do not unnecessarily burden patient or regulated entities, remain current, and reflect advances in the health care industry. We are proposing revisions to the LTC requirements that would simplify and streamline the current requirements, increase flexibility in LTC facilities, and reduce excessively burdensome requirements, while maintaining a focus on providing high quality care to residents. This proposed rule would also reduce the frequency of certain required activities, revise timeframes for certain requirements where appropriate, and remove obsolete, duplicative, or unnecessary requirements. Ultimately, these proposals balance resident safety and quality of care, while also providing regulatory relief for facilities.

B. Overall Impact

We have examined the impacts of this rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

E.O. 13771 states that it is essential to manage the costs associated with the government imposition of private expenditures required to comply with federal regulations and establishes policies and procedures to reduce the costs of both new and existing federal regulations. 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 E.O. 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 E.O.

A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget. This proposed rule contains proposals that would create ongoing cost savings to LTC facilities. Other revisions we have proposed would clarify existing policy and relieve some administrative burdens. The financial savings are summarized in the table that follows. We welcome public comments on all of our burden assumptions and estimates as well as comments identifying additional reforms that should be considered in the final rule or future rulemakings. As discussed later in this regulatory impact analysis, uncertainty surrounds these estimates and we especially solicit comments on either our estimates of likely savings or the specific regulatory revisions that drive these estimates.

C. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

We obtained the data used in this discussion on the number of Medicare and Medicaid participating LTC facilities from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of May 2018, unless indicated otherwise. We have not included data for facilities that are not Medicare or Medicaid certified. As of May 2018, there are 15,639 LTC facilities that participate in the Medicare and/or Medicaid program.

Unless otherwise indicated, we obtained all salary information from the May 2017 National Occupational Employment and Wage Estimates, United States by the BLS at *https://www.bls.gov/oes/current/oes_nat.htm* and we have calculated the estimated hourly rates in this proposed rule based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation to these overhead and fringe benefit costs. The hourly wages calculated on this basis are shown in Table 3 in Section III Collection of Information.

D. Anticipated Effects on LTC Facilities

Table 4 summarizes the expected savings to facilities from the preceding information collection reforms and the other cost savings addressed in detail in the following section of the RIA.

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Table 4. Summary of Cost Reductions*

Regulatory Provisions	Annual IC Savings	Annual Other Savings	Total Annual Savings
A. Requirements for Participation			
1. Resident Rights (§483.10)			
a. Choice of Attending Physician	NA	NA	NA
b. Grievances	NA	$78,069,888	$78,069,888
2. Admission, Transfer, and Discharge Rights (§483.15)	$1,473,047	NA	$1,473,047
3. Quality of Care (§483.25)	NA	NA	NA
4. Nursing Services (§483.35)	NA	NA	NA
5. Behavioral Health (§483.40)	NA	NA	NA
6. Pharmacy Services (§483.45)	NA	NA	NA
7. Food and Nutrition Services (§483.60)	NA	$19,142,136	$19,142,136
8. Administration (§483.70)--Facility Assessment (§483.70(e))	$13,809,237	NA	$13,809,237
9. Quality Assurance and Performance Improvement (§483.75)	$39,222,612	NA	$39,222,612
10. Infection Control (§483.80)	NA	NA	NA
11. Compliance and Ethics Program (§483.85)	$4,907,069	$109,909,488	$114,816,557
12. Physical Environment (§483.90)			
a. Life Safety Code**	NA	$48,000,000	$48,000,000

b. Resident Rooms and Bathrooms	NA	$328,000,000	$328,000,000
B. Survey, Certification, and Enforcement Procedures			
13. Informal Dispute Resolution and Independent Informal Dispute Resolution (§488.331 and §488.431)	NA	NA	NA
14. Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§488.436)***	NA	$1,233,112	$1,233,112
15. Notification of Intent to Delay Phase 3 Implementation of Overlapping Regulatory Provisions	NA	NA	NA
Totals	$59,411,965	$584,354,624	$643,766,589

* These estimates for the first full year.
** Life Safety Code cost savings of $240 million spread over five years.
*** Approximately $0.7 million of this amount is a transfer related to reduced CMPs imposed on facilities.

1. Resident Rights (§ 483.10(j))

We propose several revisions to the regulations at § 483.10(j) that require facilities to develop a grievance policy. In the October 2016 final rule, we indicated most facilities already have a

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grievance process and therefore, the cost associated with establishing a grievance policy would mainly be attributed to the requirement for a grievance official with specific duties. This rule proposes, at § 483.10(j)(4)(ii), to remove the specific duties required of the grievance official. The October 2016 final rule estimated that the regulatory burden for establishing a designated grievance official to oversee the grievance process and to perform specific duties is $156,139,776 annually (updated to reflect current salary information). The revision would eliminate the staff burden associated with the specific tasks that must be performed by the grievance official. Facilities would have the flexibility to determine how their grievance policy can be tailored to fully address grievances and establish the necessary duties of their designated grievance official.

We assume that removing the prescriptive required duties would reduce the current burden by approximately half due to the increased flexibility that would allow facilities to execute a grievance process in the most efficient manner for each facility's needs. Therefore, this proposal would result in a cost savings of $78,069,888 (5 percent of a social worker FTE × $48 hourly wage for a social worker × 2,080 hours (40 hours a week × 52 weeks) × 15,639 facilities). We request comments on this assumption.

2. Admission, Transfer, and Discharge Rights (§ 483.15)

The cost savings to facilities for proposals in this section are related to paperwork burden and discussed in detail in the Collection of Information section. We estimate a total cost savings of $1,148,503.

3. Quality of Care (§ 483.25)

The proposed revisions in the section clarify existing requirements related to the use of bedrails and have negligible effects on reducing facility costs.

4. Nursing Services (§ 483.35)

The proposed revisions in this section are related to administrative processes and any cost savings would normally be discussed in the Collection of Information section. However, as noted the proposed revisions in this section are related to record retention. While we believe that reducing the timeframe for maintaining records will produce cost savings to facilities, there are no collection of information requirements associated with this proposed change because maintaining records is considered a usual and customary practice in accordance with the implementing of regulations of the PRA 5 CFR 1320.3(b)(2). Moreover, we believe that the cost savings from the reduced duration of the daily staffing list storage requirement would be minimal, saving at most the equivalent of one file cabinet drawer of space per facility.

5. Behavioral Health (§ 483.40)

The proposed revisions in this section remove duplicative requirements and do not affect facility costs.

6. Pharmacy Services (§ 483.45)

The proposed reforms in this section are aimed to strengthen resident protections by eliminating unnecessary restrictions on prescribers' ability to tailor psychotropic prescriptions to resident needs, avoiding unnecessary delays in prescribing, and placing responsibility on facilities to develop more tailored policies on using PRN orders for psychotropic drugs. We expect that these reforms will reduce unnecessary interruptions in some residents' care while preserving needed resident protections. We do not expect significant changes in either costs or benefits and have not attempted to make a quantitative forecast of either.

7. Food and Nutrition Services (§ 483.60)

We propose to revise the required qualifications for a director of food and nutrition services to provide that those with several years of experience performing as the director of food and nutrition services in a facility can continue to do so. This is a major change from the October 2016 final rule, which added credentialing requirements for the director of food and nutrition services to include being a ''certified food service manager,'' or ''certified dietary manager,'' or ''has similar national certification . . . from a national certifying body,'' or has an associate's or higher degree in food service or restaurant management. Under the October 2016 final rule, a significant fraction of current directors of food and nutrition services would have had to be replaced or, at great expense, have had to attend an institution of higher education to obtain required credential.

The current annual cost for the director of food and nutrition services is an estimated $122,400 annually (updated to reflect current salary information and including fringe benefits and overhead costs). We previously estimated that 10 percent of facilities would need to pursue additional candidates that meet the new qualifications for a director of food and nutrition services. Assuming that, on average, there is a 10 percent wage differential between those with experience but no further credential, and those who would have met the standards of the October 2016 final rule for director of food and nutrition services either as specified in that rule, or by meeting the even higher standards for ''qualified dietician,'' this means that removing those standards would reduce costs to facilities by $19,142,136 (10 percent of 15,639 facilities × $12,240). In this calculation, the wage differential is assumed to be only about 10 percent because there are offsetting costs to the facility for retaining staff who are qualified by experience but who may need expert help, such as the proposed requirement for frequently scheduled consultation with a qualified dietician. We welcome comments on these estimates and additional information that would help us improve them.

We propose that at a minimum an individual designated as the director of food and nutrition services receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional; and has 2 or more years of experience in the position of a director of food and nutrition services, or has completed a minimum course of study in food safety. These revisions would provide an experience qualifier that would likely eliminate the need for many facilities to hire additional or higher salaried staff.

8. Administration (483.70)

We discuss the economic impact for the administration requirement in the ICR section of this rule. We estimate $13,840,515 in savings.

9. Quality Assurance and Performance Improvement Program (§ 483.75)

This rule proposes to revise the requirements in § 483.75 to provide facilities with the flexibility needed to tailor their QAPI programs to the individual needs of their specific facility. Specifically, we have proposed to remove the prescriptive requirements at § 483.75(b)(1) through (4), and § 483.75(c)(1) through (4), and all of the requirements in § 483.75(d)(2). A detailed discussion of the proposed removal of these requirements can be found in section II.A.

The proposed removal of these prescriptive requirements would focus the QAPI requirements on the expected results of the program and would no longer prescribe the structures and methods for implementing the QAPI program. This provides flexibility to the facility, as it is free to develop a creative program that meets the needs of the

facility and reflects the scope of its services and operations. We discuss the economic impact for the QAPI program in the ICR section of this rule, which represents $39,222,612 in savings.

10. Infection Control (§ 483.80)

We have proposed changing the requirement that the infection preventionist work at the facility ''part-time'' or have frequent contact with the infection prevention and control program staff at the facility, to instead require that the facility ensure that the IP has sufficient time to meet the objectives of its IPCP. Because this is more of a clarification than a change in policy, we do not anticipate any measurable impact from this revision.

11. Compliance and Ethics Program (§ 483.85(d))

We propose to reduce cost to facilities by eliminating the requirement for a dedicated compliance officer and a compliance liaison. We estimated that in carrying out this program the compliance officer (similar to an administrator) in each of the 422 organizations operating 5 or more facilities will commit 30 percent of a full time equivalent (FTE) in the compliance program operation, for a total cost of $23,436,192 (30 percent of FTE × 2080 × $89 × 422). We also estimate that in carrying out this program the compliance liaison (nursing staff) in each of 6,599 facilities will commit 10 percent of an FTE, at a total cost of $86,473,296 (10 percent of FTE × 2080 × $63 × 6,599). As such, by removing these requirements, we estimate annual savings of $109,909,488. We discussed the burden reduction for our proposed revision of the compliance and ethics program plan requirements imposed on LTC facilities in the ICR section of this rule, which estimates annual savings of $13,716,734. We estimate total annual savings for these requirements together of $123,626,222.

12. Physical Environment

Life Safety Code § 483.90(a)

At § 483.90(a) we are proposing to allow those existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment and people movement requirements. This would allow existing LTC facilities that previously met the FSES requirements to continue to do so without incurring great expense to change construction type—essentially undertake an effort to completely rebuild. Facilities may request a waiver of certain life-safety code requirements. The request and subsequent approval of such a waiver would constitute compliance with the Life Safety Code.

While we do not have information on the number of facilities that undertake reconstruction in a given year, we can estimate the number of facilities placed at risk of a deficiency citation by these requirements, and thus the risk of being required to rebuild the structure in order to update the building's construction type, by considering the age of the facility and the building methodologies used in given time periods. We consulted with CMS Regional Office survey staff, and based on information received from them, we estimate that 50 facilities are directly impacted by the change in the scoring of the FSES and would no longer achieve a passing score on the FSES. We estimate the average size of the affected nursing homes to be roughly 25,000 sq. ft. The cost of construction per sq. ft. is estimated at $180 in 2013 dollars (*https://www.rsmeans.com/model-pages/nursing-home.aspx*). Assuming a construction cost increase over this period of 6.5 percent using GDP deflator, the 2017 construction cost per square foot would be about $192 a square foot. The total savings from this proposal in 2017 dollars would be approximately $240 million (25,000 sq. ft. × $192 per sq. ft. × 50 facilities).

This estimate assumes that essentially all these facilities would be replaced. There are two major and offsetting trends affecting the nursing home care market in coming decades: The increasing preference and ability of elderly and disabled adults to finance and obtain long term nursing care in their own homes, and the increasing number of elderly and disabled adults as the baby boom population ages. Assuming, absent specific evidence, that these two trends roughly offset each other, the preceding estimates are a reasonable projection of likely investment costs in new (or totally reconstructed) facilities. For purposes of annual cost estimates, we assume that those costs would be spread over 5 years, and would therefore be approximately $48 million annually in those years ($240 million/5 years). There are additional uncertainties in these estimates and we therefore provide estimates that are 25 percent lower and higher in the Accounting table near the end of this RIA.

Bathroom Facilities § 483.90(f)

We are proposing to revise § 483.90(f) regarding bathroom facilities, to apply only to newly constructed facilities and newly certified facilities that have never previously been a long-term care facility. The cost of remodeling or installing a bathroom where there is none requires a substantial amount of work in some cases and may cause facilities to decide not to reopen or that the upgrade is not worth the cost. Sometimes when a facility is terminated, a new owner will come in and get newly certified. Under current requirements, the new owners would have to make the upgrades, which often times discourages new ownership (*https://www.rsmeans.com/model-pages/nursing-home.aspx*).

We estimate that there are 150 terminations per year, which we will assume come back into the program eventually under the same ownership with a new Medicare Identification Number, and that two-thirds (that is, 100) of these would have required bathroom installations. We also assume that there are 700 changes of ownership per year without the transfer of a Medicare Identification Number and provider agreement, of which about two-thirds (that is, 470) would require remodeling the bathrooms. The two-thirds estimate is an assumption based on the lack of state requirements requiring bathrooms adjacent to resident rooms. In each of the scenarios above, facility closure or the change of ownership without the transfer of a Medicare Identification Number and provider agreement necessitates reapplication for enrollment in the Medicare program. Therefore the facilities would be considered newly certified, triggering the requirements at §§ 483.90(e)(1)(i) and (f). For a wheelchair accessible bathroom with 2 fixtures (a commode and sink) the average square footage is 60 square feet. The average cost of construction per square foot was $180 in 2013 according to RSMeans construction cost data (again, *https://www.rsmeans.com/model-pages/nursing-home.aspx*). Assuming a construction cost increase over this period of 6.5 percent using the GDP deflator, the 2017 construction costs per square foot would be about $192 a square foot. The average number of residents per facility is 100/2 persons per room, giving an average of 50 bathrooms per facility. Therefore, we estimate the total first year savings for this proposal would be $576,000 based on the following: 60 sq. ft. per bathroom × 50 bathrooms × $192 per sq. ft. (inflating to 2017 dollars) = $576,000

per facility ($11,520 per room). These costs divide among terminations and change of ownership as follows:

Terminations: 100 × $576,000 = $57,600,000.

Change of Ownership: 470 × $576,000 = $270,720,000.

These calculations lead to a total first year savings estimate of $328,000,000 ($57,600,000 + $270,720,000). Second and future year savings would, however, be lower because the proportion of the existing facilities needing bathroom upgrades would have decreased each year under the October 2016 final rule. The combined number of estimated terminations and changes of ownership receiving these upgrades of 570 per year under the October 2016 final rule represents about 4 percent of the baseline stock. Presumably the likely savings from repeal of this requirement would therefore be lower by about 4 percent each year than in the year before (compounding over time as the baseline stock with such bathrooms increases). Our Accounting table's annualized estimates make this adjustment. Also, as previously described, our accounting table provides high and low estimates that are 25 percent higher or lower to emphasize the uncertainty in these estimates.

13. Informal Dispute Resolution and Independent Informal Dispute Resolution (§ 488.331 and § 488.431)

While the proposed provisions regarding the IDR and Independent IDR processes would not have significant financial burden reduction for providers, addressing issues related to the timeliness and transparency of these procedures could potentially save time and money for providers, the States, and CMS. In 2016, the completion time for the IDR process ranged from 1 day to 519 days with a median of 21 days. Providers are now required to pay CMPs into an escrow account where they are held pending a final administrative decision. For smaller facilities, having what could be a substantial amount of money held in escrow for more than a year could cause financial burden on the facility. Requiring that the process be completed in 60 days, consistent with the Independent IDR procedure, would result in a more timely return of the money being held in the case where the provider was successful in their appeal. This would also result in a financial savings to CMS as we are required to return the CMP with interest when the facility is successful. While it is impossible to place an exact dollar amount on these savings, in 2016, facilities were found non-culpable in the incidents that resulted in citations in 6 percent of IDR decisions and 12 percent of Independent IDR decisions.

The proposal specifying when the survey results should be uploaded into CASPER could not only potentially have a positive financial impact on providers but it could also have a positive impact on SAs' workload. As previously cited, in 2016, 47.31 percent of IDRs resulted in a change to the original citations. As a result of Independent IDRs, 21.8 percent of original citations were changed in some manner. If the survey results were uploaded to CASPER prior to the completion of these processes, the results could negatively impact a facility's Five-Star Quality Rating, which could not only result in a loss of business but a financial loss as well. For example, we are aware that there are payments as well as accreditation from certain organizations that are directly affected by the facility's Five-Star Quality Rating. Again, it is not possible to put a dollar amount on these savings as not all changes made based on these processes would have an impact on Five-Star Quality Ratings. For the SAs, if the information was entered prior to the completion of these processes, they would have to go back and correct any changes resulting from these processes which is valuable time that could be spent on other duties more beneficial to the protection of nursing home residents.

The proposal specifying that facilities must be provided with a written record of the final Independent IDR decision, including the Independent IDR reviewer's recommendation and, in the case where the State or CMS disagrees with that recommendation, a rationale for the disagreement, would reduce burden on providers, the States, and CMS by promoting transparency in the Independent IDR process. Providers would be given information needed to understand the final decision and no further investigation on their part would be necessary. The States and CMS would not have to respond to requests for more information as everything would be provided in the written record.

Finally, the proposal to specify that, in order to be approved as an Independent IDR reviewer, a component of an umbrella agency must have a specific understanding of Medicare and Medicaid requirements would avoid the potential for Independent IDR decisions to be challenged based on the inadequate qualifications of a reviewer. This could provide financial benefit to both providers and to CMS by avoiding unnecessary litigation. However, we have no basis for a savings calculation.

14. Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

Current requirements at § 488.436(a) set forth a process for submitting a written waiver of a hearing which, when properly filed, results in the reduction by CMS or the State of a facility's CMP by 35 percent, as long as the CMP has not also been reduced by 50 percent under § 488.438. We propose to restructure the waiver process by establishing a constructive waiver at § 488.436(a) that would operate by default when CMS has not received a timely request for a hearing. Since a large majority of facilities facing CMPs typically file the currently required express, written waiver, this proposed change to provide for a constructive waiver (after the 60-day timeframe in which to file an appeal following notice) would reduce the costs and paperwork burden for most facilities.

In CY 2016, 81 percent of facilities facing CMPs filed an express waiver; whereas only 4 percent of facilities facing CMPs filed an appeal and went through the hearing process. The remaining 15 percent of facilities are those who fail to waive at all or fail to waive timely when they do not appeal. We estimate that moving to a constructive waiver process would eliminate the time and paperwork necessary to complete and send in a written waiver and would thereby result in a total annual savings of $1,108,226 for LTC facilities facing CMPs as estimated in the following savings estimates ($381,800 plus $726,426 = $1,108,226).

We estimate that, at a minimum, facilities would save the routine cost of preparing and filing a letter (estimated at $200 per letter) to waive their hearing rights. In CY 2016, there were 2,360 facilities who faced CMPs. Roughly 81 percent (1,909) of these facilities filed an express, written waiver, therefore, we estimate an annual savings of $381,800 (1,909 × $200) since such letters would no longer be required to receive a 35 percent penalty reduction.

In addition, we believe that nationally some 15 percent of facilities fail to submit a waiver even though they had no intention of contesting the penalty and its basis. Under the proposed change to offer a constructive waiver by default, this 15 percent of facilities would now be eligible for the 35 percent cost reduction. We note that in CY 2016, CMS imposed a combined total of $116,387,898 in per day and per instance CMPs, with a median total amount due of $5,863. Since CMS imposed CMPs on 2,360 facilities in CY

2016, we estimate a cost savings for 354 facilities (15 percent of 2,360), the typical 15 percent who fail to submit a timely waiver request. We estimate the annual cost savings for these facilities at $726,426 ((35 percent × $5,863) × 354 facilities). For accounting purposes, this is considered a transfer between LTC facilities and the federal government.

Furthermore, we believe that the proposal to offer facilities a default constructive waiver process would also ease the administrative burden for the CMS Regional Offices. Based on our knowledge and experience, we estimate that, together, an array of individuals in each CMS Regional Office collectively spend close to 1 hour (0.80 hours) per CMP imposed to track and manage receipt of paperwork from facilities expressly requesting a waiver. Given that in CY 2016, CMS imposed a total of 2,858 CMPs on 2,360 facilities, with an average of 1.21 CMPs per facility, we estimate that CMS Regional Offices spend a total of 1,848 hours each year (0.80 hours per CMP × 1,909 facilities × 1.21 CMPs per facility) to manage the waiver paperwork. As previously noted, in CY 2016 we saw that 81 percent (1909) of the 2,360 facilities facing CMPs submitted written waivers. Because the activities involved in processing facilities' waivers requires input from individuals at varying levels within CMS, we base our estimate on the rate of $68.12 per hour on average, assuming a GS–12, step 5 salary rate of $34.06 per hour with a 100 percent benefits and overhead package. Thus, we estimate that CMS would save $125,886 per year ($68.12 per hour × 1,848 hours per year).

Total annual savings from these reforms to facilities and the federal government together would therefore be $1,233,112 ($381,800 plus $726,426 plus $125,886).

15. One-Time Implementation Costs

All of the proposals presented in the preceding analysis and detailed regulatory language changes will necessarily have to be read, understood, and implemented by affected providers. This will create one-time costs even though the underlying change reduce burden. In most cases these costs will be very low, and may be as simple as observing that a particular procedure will need only to be performed once rather than twice a year, and changing the schedule accordingly. In some cases, the facility will need to adjust in response to multiple burden reduction changes. In still other cases, time will have to be spent deciding how to change existing policy.

In total, there are about 15,639 affected entities. We assume that on average there will be 1 hour of time spent by a lawyer, 2 hours of time by facility administrator, and 2 hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further estimate that 2 hours of director of nursing or facility administrator time and 2 hours of clerical time will be needed to direct and communicate changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are $136 for attorneys, $89 for director of nursing, $63 for registered nurses, $89 for facility administrator, and $31 for office assistant. These hourly estimates are from Table 3 and the underlying data are taken from BLS statistics for 2017, at *https://www.bls.gov/oes/current/oes_nat.htm#39-0000.*

The estimated costs for an average facility would be 1 hour at $136 and in total for attorney time, 4 hours at $89 or $356 in total for the facility administrator and director of nursing, 2 hours of time at $31 or $62 in total for clerical work, and 2 hours of time at $63 or $126 in total for other staff (RN hourly wage). For all facilities these costs add up to 15,639 times. These one-time costs add up to $680 per facility on average ($136 + $356 + $62 + $126), and in total to about $11 million (680 × 15,639 LTC facilities).

E. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all LTC facilities regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The majority of long term care facilities and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). Accordingly, the savings in this proposed rule would create benefits for small entities.

The RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be prepared if a proposed rule would have a ''significant impact on a substantial number'' of such entities. HHS interprets the statute as mandating this analysis only if the impact is adverse, though there are differing interpretations. Regardless, there is no question that this proposed rule would affect a ''substantial number'' of small entities. The rule of thumb used by HHS for determining whether an impact is ''significant'' is an effect of 3 percent or more of annual revenues. These savings do not approach that threshold for most of the affected facilities. However, for those facilities that would benefit from the reforms proposed for physical environment standards, savings would far exceed the 3 percent threshold. We estimate that over one thousand facilities would benefit from these particular reforms, with total savings to these facilities exceeding $800 million in the first year. Accordingly, we have concluded that the economic effects of this proposed rule would have a significant beneficial effect on a substantial number of small entities. This RIA, together with the remainder of the preamble, meets the standards for an IRFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603. 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 affects only LTC facilities and will not have any direct impacts on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from (A) imposing enforceable duties on state, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement

programs. This proposed rule contains no such mandates.

E.O. 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule would impose no such requirements.

F. Effects on Costs to Facilities, Providers, Medicare, Medicaid, and Patients

The immediate effects of these proposed reforms will benefit nursing facilities by reducing their costs, in some cases quite substantially, as estimated earlier in this RIA.

This proposed rule has no direct effects on the Medicare or Medicaid programs. Medicaid, however, pays for the majority of LTC costs, with more than 60 percent of residents having Medicaid as their primary payer. Medicare pays for a substantial fraction of skilled nursing care provided at these same facilities. Medicaid payment rates are set by states and it is likely that over a period of time facility savings will affect State decisions on future rates. However, there is no one-to-one correspondence. Likewise, Medicare payment rates for skilled nursing care are set based on statutory formulas and do not rapidly respond to changes in cost of care at any particular facility. It is likely, however, that in the long run most of these burden reduction savings will reduce taxpayer costs, both federal and state, under the Medicaid and Medicare programs. Private payers, both private insurance and many patients, will also benefit, but to a lesser extent since their share of nursing facility costs is relatively small.

We have not attempted to estimate effects on patients at these facilities. We do not believe that any substantial increases or reductions in the quality of patient care will result. Freeing up staff resources that are unreasonably burdensome will free up staff time available for beneficial services, but these effects are likely small and not practical to estimate. We welcome comments, however, that focus on patient care issues.

G. Alternatives Considered

Throughout this preamble we have raised issues of regulatory costs. Those reforms we have proposed are those that in our view are most likely to produce significant savings without jeopardizing patient care in any way. Indeed, reductions in unnecessary red tape free up facility resources to focus on patient care. We used the May 2017 RFI comments and previous public comments on prior rules extensively in developing these proposals.

Some specific alternative proposals we considered include modifications to the requirements for the infection preventionist to reduce costs and increase access. Ultimately, we considered current events and recent reports (as discussed in the infection control section) that indicate the prevalence of infection control concerns within nursing homes and determined it would not be appropriate to propose robust revisions to the infection control requirements at this time. Second, we considered not proposing any revisions the PRN requirements for anti-psychotic medications. However, based on concerns raised by commenters, especially the challenges highlighted by psychiatric professionals (as discussed in the pharmacy services section) we determined that a balance between resident safety and access to appropriate medications is necessary and we have solicited comment on this proposal for further insight.

Lastly, we considered not proposing any burden reducing proposals for nursing homes at this time, given that the 2016 final rule has not been fully implemented yet. However, we considered the comments received as part of the May 2017 RFI and those responses to the 2016 final rule, and determined that some modifications to the recent requirements would be appropriate at this time.

This said, there may well be significant reform options that we have not directly identified. We strongly encourage comments not only on the proposals identified in this rule, but also on other existing regulatory requirements, both to improve these proposals and to identify other beneficial reforms that we did not specifically identify. In particular, we request comments on other changes made in the 2016 final rule that could be revised or eliminated to reduce unnecessary burden.

H. Accounting Statement and Table

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 5, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule. As previously discussed, there are no costs that would be created under this proposed rule, and minimal transfer payments. There likely would be some benefits to residents from freeing up staff to focus on resident care rather than unnecessary paperwork and other burdens, but these are likely to be small and cannot be estimated. The primary estimate shown in this table is lower than our estimate of as much as $644 million annually in the first 5 years because we estimate that the LSC cost savings will be achieved only during the first 5 years and our annualized estimate covers 10 years. Totals are rounded to the nearest $10 million.

Table 5. Accounting Statement: Classification of Estimated Savings ($millions)

Category	Primary Estimate	Lower Bound	Upper Bound	Units		
				Year Dollars	Discount Rate	Period Covered
Benefits	None Quantifiable					
Annualized Monetized Costs (+) or Cost Reductions (-)	-$580	-$430	-$720	2017	7%	2019-2028
	-$570	-$430	-$710	2017	3%	2019-2028
Transfers	$0*					

* There is a transfer related to the costs of submitting waiver requests in the analysis of Civil

I. Reducing Regulation and Controlling Regulatory Costs

E.O. 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule will, if finalized as proposed, be considered an E.O. 13771 deregulatory action. We estimate that this rule generates $392 million in annualized cost savings in 2016 dollars, discounted at 7 percent relative to year 2016, over a perpetual time horizon. Details on the estimated cost savings from this rule can be found in the preceding analysis.

J. Conclusion

This proposed rule would substantially reduce existing regulatory requirements imposed on LTC facilities through the CoPs that Medicare and Medicaid providers must meet. The analysis in this RIA section, together with the remainder of this preamble, provides a complete RIA as well as a complete IRFA.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas X-rays.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

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 proposes to amend 42 CFR chapter IV as set forth in Requirements for states and long term care facilities:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd).

§ 410.32 [Amended]

■ 2. Section 410.32 is amended in paragraph (d)(1)(vii) by removing the reference ''§ 483.75(k)(1)(i)'' and adding in its place the reference ''§ 483.50(a)(1)(i)''.

§ 410.78 [Amended]

■ 3. Section 410.78 is amended in paragraph (e)(2) by removing the reference ''§ 483.40(c)'' and adding in its place the reference ''§ 483.30(c)''.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

§ 482.58 [Amended]

■ 2. Section 482.58 is amended in paragraph (b)(5) by removing the reference ''483.40(d)'' and adding in its place the reference ''§ 483.40(c)''.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 3. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

■ 4. Section 483.10 is amended by revising paragraphs (d)(3), (f)(11)(i)(F), (j)(1) and (2), and (j)(4)(i), (ii), (v), and (vii) to read as follows:

§ 483.10 Resident rights.

* * * * *

(d) * * *

(3) The facility must provide the primary care physician's name and contact information upon admission,

with any change of such information or upon the resident's request.

* * * * *

(f) * * *

(11) * * *

(i) * * *

(F) Medically-related social services as required at § 483.40(c).

* * * * *

(j) * * *

(1) The resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay that differ from general feedback from residents or their resident representative.

(2) The resident has the right to and the facility must make prompt efforts to resolve grievances the resident may have, in accordance with this paragraph (j).

* * * * *

(4) * * *

(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State Agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;

(ii) Identifying an individual who is responsible for overseeing the grievance process.

* * * * *

(v) Ensuring that all written grievance decisions include any pertinent information including but not limited to a summary of the findings or conclusions and any corrective action taken or to be taken by the facility as a result of the grievance;

* * * * *

(vii) Maintaining evidence demonstrating the results of all grievances for a period of no less than 18 months from the issuance of the grievance decision.

* * * * *

■ 5. Section 483.15 is amended—

■ a. In paragraph (c)(1)(ii) by removing the reference ''§ 431.220(a)(3)'' and adding in its place ''§ 431.220(a)(2)''; and

■ b. By revising paragraph (c)(3)(i).

The revision reads as follows:

§ 483.15 Admission, transfer, and discharge rights.

* * * * *

(c) * * *

(3) * * *

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. For facility-initiated involuntary transfers or discharges, other than emergency transfers to an acute care facility when return is expected, the facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

* * * * *

■ 6. Section 483.25 is amended by revising paragraphs (n) introductory text and (n)(1) and (2) to read as follows:

§ 483.25 Quality of care.

* * * * *

(n) *Bed rails.* The facility must attempt to use appropriate alternatives prior to the use of a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

(1) Assess the resident for risk of entrapment from bed rails use.

(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to use.

* * * * *

■ 7. Section 483.35 is amended—

■ a. In paragraph (a)(2) by removing the reference ''paragraph (c)'' and adding in its place ''paragraph (e)'';

■ b. In paragraph (e)(4) by removing the reference ''paragraph (c) of this section'' and adding in its place ''this paragraph (e)'';

■ c. In paragraph (f)(2) by removing the reference ''paragraph (d)(1)'' and adding in its place ''paragraph (f)(1)''; and,

■ d. By revising paragraph (g)(4).

The revision reads as follows:

§ 483.35 Nursing services.

* * * * *

(g) * * *

(4) *Facility data retention requirements.* The facility must maintain the posted daily nurse staffing data for a minimum of 15 months, or as required by state law, whichever is greater.

■ 8. Section 483.40 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing paragraph (c); and

■ c. Redesignating paragraph (d) as paragraph (c).

The revision reads as follows:

§ 483.40 Behavioral health services.

* * * * *

(a) In accordance with § 483.35, the facility must have sufficient staff who provide direct services to residents with competencies and skills sets that include, but are not limited to, knowledge of and appropriate training and supervision for:

* * * * *

■ 9. Section 483.45 is amended by revising paragraphs (e)(4) and (5) to read as follows:

§ 483.45 Pharmacy services.

* * * * *

(e) * * *

(4) PRN orders for psychotropic drugs are limited to 14 days. If the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, the order can be extended in accordance with facility policy if he or she documents his or her rationale in the resident's medical record and indicates the duration for the PRN order.

(5) It develops and maintains policies, standards, and procedures regarding the use of PRN orders for psychotropics, using recognized standards of practice, including the circumstances in which PRN orders for psychotropic drugs can be extended beyond 14 days. The policy must:

(i) Take into consideration the facility's resident population, the individual residents' needs for psychotropic drugs, and their access to physicians and other health care practitioners; and

(ii) Include, at a minimum, the following elements:

(A) Standards regarding the frequency with which the attending physician or the prescribing practitioner must review the PRN order. The frequency of PRN review must be no less than the frequency of the required physician visits as set forth at § 483.30(c).

(B) Documentation requirements regarding the diagnosis, indications for use, including nursing documentation describing the circumstances that support the administration of the medication, and justification for prolonged use.

(C) Disclosure requirements that the facility must make to the resident and

his or her representative for when a resident is prescribed an anti-psychotic.

* * * * *

■ 10. Section 483.60 is amended by revising paragraph (a)(2) to read as follows:

§ 483.60 Food and nutrition services.

* * * * *

(a) * * *

(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services.

(i) The director of food and nutrition services is one who at a minimum—

(A) Has two or more years of experience in the position of director of food and nutrition services in a nursing facility setting or;

(B) Has completed a course of study in food safety and management that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving.

(ii) The director of food and nutrition services must receive frequently scheduled consultation from a qualified dietitian or other clinically qualified nutrition professional.

* * * * *

■ 11. Section 483.70 is amended by revising paragraph (e) introductory text and by removing paragraph (e)(3).

The revision reads as follows:

§ 483.70 Administration.

* * * * *

(e) *Facility assessment.* The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must, in coordination with §§ 483.35, 483.40(a), 483.60(a), and 483.75, utilize information collected under the facility assessment to inform policies and procedures; review and update that assessment, as necessary, and at least biennially; and review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

* * * * *

■ 12. Section 483.75 is amended by revising paragraphs (b), (c), and (d) to read as follows:

§ 483.75 Quality assurance and performance improvement program.

* * * * *

(b) *Program design and scope.* A facility must design its QAPI program to be ongoing, comprehensive, and capable of addressing the full range of care and services provided by the facility.

(c) *Program feedback, data systems and monitoring.* A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring.

(d) *Program systematic analysis and systemic action.* The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

* * * * *

■ 13. Section 483.80 is amended by revising paragraph (b)(3) to read as follows:

§ 483.80 Infection control.

* * * * *

(b) * * *

(3) Have sufficient time at the facility to achieve the objectives set forth in the facility's IPCP.

* * * * *

■ 14. Section 483.85 is revised to read as follows:

§ 483.85 Compliance and ethics program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Compliance and ethics program means, with respect to a facility, a program of the operating organization that—

(i) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

(ii) Includes, at a minimum, the required components specified in paragraph (c) of this section.

High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.

Operating organization means the individual(s) or entity that operates a facility.

(b) *General rule.* Beginning on November 28, 2019, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

(c) *Required components for all facilities.* The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act.

(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures.

(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others within the operating organization without fear of retribution.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to

detect and report a violation (statute says, ''offense'') to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

(9) The facility has an alternate method of reporting suspected violations anonymously.

(d) *Additional required components for operating organizations with five or more facilities.* In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities and facilities with corporate level management of multi-unit nursing home chains must comply with these additional requirements must:

(1) Have a more formal program that includes established written policies defining the standards and procedures to be followed by its employees.

(2) Develop a compliance and ethics program that is appropriate for the complexity of the operating organization and its facilities.

(e) *Program review.* The operating organization for each facility must periodically review and revise its compliance program to identify necessary changes within the organization and its facilities.

■ 15. Section 483.90 is amended by adding paragraph (a)(1)(iii) and revising paragraphs (d), (e)(1)(i), and (f) to read as follows:

§ 483.90 Physical environment.

* * * * *

(a) * * *

(1) * * *

(iii) If a facility is Medicare- or Medicaid-certified before July 5, 2016 and the facility has previously used the Fire Safety Evaluation System for compliance, the facility may use the scoring values in table 1 to § 483.90(a)(1)(iii):

Table 1 to § 483.90(a)(1)(iii): Mandatory Values—Nursing Homes

	Containment (Sa)		Extinguishment (Sb)		People Movement (Sc)	
Zone Location	New	Exist.	New	Exist.	New	Exist.
1st story	11	5	**15(12)***	4	**8(5)***	1
2nd or 3rd story **	15	9	**17(14)***	6	**10(7)***	3
4th story or higher	18	9	**19(16)***	6	**11(8)***	3

* Use ( ) in zones that do not contain patient sleeping rooms.

* * * * *

(d) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care; and

(2) Maintain all mechanical, electrical, and patient care equipment in safe operating condition.

(3) Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible.

(e) * * *

(1) * * *

(i) Accommodate no more than four residents. For facilities that receive approval of construction plans by state and local authorities or are newly certified and have never previously been a LTC facility, after November 28, 2016, bedrooms must accommodate no more than two residents.

* * * * *

(f) *Bathroom facilities.* Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction from state and local authorities or are newly certified and have never previously been a LTC facility, after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and sink.

* * * * *

■ 16. Section 483.95 is amended by revising paragraph (f) to read as follows:

§ 483.95 Training requirements.

* * * * *

(f) *Compliance and ethics.* The operating organization for each facility must include as part of its compliance and ethics program, as set forth at § 483.85, an effective way to communicate that program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 17. The authority citation for part 485 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh)).

■ 18. Section 485.645 is amended by revising paragraphs (d)(3) and (5) to read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'').

* * * * *

(d) * * *

(3) Freedom from abuse, neglect and exploitation (§ 483.12(a)(1) and (2), (a)(3)(i) and (ii), (a)(4), (b)(1) and (2), and (c)(1) through (6) of this chapter).

* * * * *

(5) Social services (§§ 483.40(c) and 483.70(p) of this chapter).

* * * * *

PART 488—SURVEY, CERTIFICATION AND ENFORCEMENT PROCEDURES

■ 19. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 20. Section 488.331 is amended by revising paragraph (b) to read as follows:

§ 488.331 Informal dispute resolution.

* * * * *

(b)(1) Informal dispute resolution will be completed within 60 days of the facility's request to dispute the survey findings if the request by the facility is timely. Failure of the state or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action, except that the results of the survey will not be uploaded into the CMS nursing home survey and certification database and/or used for the purposes of the CMS ''Nursing Home Compare'' website to calculate the facility's 5-star rating until the informal dispute resolution or the independent informal dispute resolution process is complete.

* * * * *

■ 21. Section 488.431 is amended by revising paragraphs (a)(2) and (a)(4)(i) to read as follows:

§ 488.431 Civil money penalties imposed by CMS and independent informal dispute resolution: for SNFs, dually-participating SNF/NFs, and NF-only facilities.

(a) * * *

(2) Generate a written record prior to the collection of the penalty. The state, or CMS, as applicable, will provide the facility with a written notification of the independent reviewer's recommendation and the final decision, including a rationale for that decision.

* * * * *

(4) * * *

(i) A component of an umbrella state agency provided that the component is organizationally separate from the State survey agency and has a specific understanding of Medicare and Medicaid program requirements.

* * * * *

■ 22. Section 488.432 is amended by revising paragraph (c)(2) to read as follows:

§ 488.432 Civil money penalties imposed by the State: NF-only.

* * * * *

(c) * * *

(2) If a facility waives its right to a hearing as specified in § 488.436, the state initiates collection of civil money penalty imposed per instance of noncompliance after 60 days and the state has not received a timely request for a hearing.

* * * * *

■ 23. Section 488.436 is amended by revising paragraph (a) to read as follows:

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Constructive waiver of a hearing.* A facility is deemed to have waived its right to a hearing after 60 days if CMS has not received a request for a hearing from the facility.

* * * * *

■ 24. Section 488.442 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) * * *

(2) *After the facility waives its right to a hearing in accordance with § 488.436(a).* Except as provided for in § 488.431, a civil money penalty is due 75 days after the notice of the penalty and a hearing request was not received when:

* * * * *

Dated: June 24, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–14946 Filed 7–16–19; 4:15 pm]

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