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DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 103

[CIS No. 2652–19; DHS Docket No. USCIS–2019–0006]

RIN 1615–AC36

Registration Fee Requirement for Petitioners Seeking To File H–1B Petitions on Behalf of Cap Subject Aliens

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends Department of Homeland Security (DHS) regulations to require petitioners seeking to file H–1B cap-subject petitions to pay a $10 fee for each registration they submit to U.S. Citizenship and Immigration Services (USCIS) for the H–1B cap selection process.

DATES: This final rule is effective December 9, 2019.

FOR FURTHER INFORMATION CONTACT: Charles Nimick, Chief, Business & Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW, Suite 1100, Washington, DC 20529–2140; Telephone (202) 272–8377.

SUPPLEMENTARY INFORMATION:

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I. Background

A. The H–1B Registration System

On January 31, 2019, DHS published a final rule requiring petitioners seeking to file H–1B cap-subject petitions, including those eligible for the advanced degree exemption, to first electronically register with USCIS during a designated registration period, unless the requirement is suspended (''H–1B registration final rule'').[1] USCIS stated in the H–1B registration final rule that it was suspending the registration requirement for the fiscal year 2020 cap season to complete required user testing of the new H–1B registration system and otherwise ensure the system and process work correctly.

Once USCIS implements the system and requires registration, USCIS will not consider an H–1B cap-subject petition to be properly filed unless it is based on a valid registration selection for the applicable fiscal year. *See* 8 CFR 214.2(h)(8)(iii)(A)(*1*) and (h)(8)(iii)(D). USCIS will reject or deny H–1B cap-subject petitions that are not properly filed. 8 CFR 214.2(h)(8)(iii)(D).

B. Legal Authority

The Immigration and Nationality Act (INA) authorizes DHS to establish and collect fees for adjudication and naturalization services to ''ensure recovery of the full costs of providing all such services, including the costs of similar services provided without charge to asylum applicants or other immigrants.'' INA section 286(m), 8 U.S.C. 1356(m). Through the collection of fees established under that authority, USCIS is primarily funded by immigration and naturalization fees charged to applicants, petitioners, and other requestors. *See* INA sections 286(m) and (n), 8 U.S.C. 1356(m) and (n); 8 CFR 103.7(b)(1)(i)(USCIS fees). Fees collected from individuals and entities filing immigration benefit requests are deposited into the Immigration Examinations Fee Account (IEFA) and used to fund the cost of processing immigration benefit requests.[2] Consistent with that authority and USCIS' reliance on fees for its funding, DHS is amending its regulations to require a fee for submitting H–1B registrations.

C. Registration Fee

On September 4, 2019, DHS published a notice of proposed rulemaking seeking public comments on its proposal to require a $10 fee per H–1B registration. *See* 84 FR 46460. DHS is amending its regulations to require a $10 fee for each registration submitted to register for the H–1B cap selection process. See 8 CFR 103.7(b)(1)(i)(NNN). As stated in the proposed rule, USCIS operations are funded by fees collected for adjudication and naturalization services, and USCIS must expend resources to implement and maintain the registration system. Therefore, DHS is requiring a fee for submitting H–1B registrations to recover those costs.

II. Public Comments on the Proposed Rule

A. Summary of Public Comments

In response to the proposed rule, DHS received 22 comments during the 30-day public comment period. There were no duplicate submissions or letters submitted through mass mailing campaigns. DHS considered all of these comment submissions. Commenters consisted of individuals (including U.S. workers), law firms, professional organizations, and advocacy groups. Some commenters expressed support for the rule and/or offered suggestions for improvement. Two commenters expressed general opposition to the rule, suggesting that DHS should not impose a fee for registration. For many of the public comments, DHS could not ascertain whether the commenter supported or opposed the proposed rule. A number of comments received addressed subjects beyond those covered by the proposed rule, and were deemed out of scope.

DHS has reviewed all of the public comments received in response to the proposed rule and is addressing relevant comments in this final rule. DHS's responses are grouped by subject area,

[1] *See* 84 FR 888 (Jan. 31, 2019); 8 CFR 214.2(h)(8)(iii)(A)(*1*).

[2] *See* 81 FR 26904, 26905 (May 4, 2016).

with a focus on the most common issues and suggestions raised by commenters. DHS is not addressing comments seeking changes in U.S. laws, regulations, or agency policies that are out of scope and unrelated to the changes proposed on September 4, 2019, or to the H–1B registration system generally.

B. General Support for the Proposed Rule

Comment: Two commenters stated that they agreed with the proposed fee without providing any additional or substantive rationale. While DHS appreciates the input, a response to these general support comments is not necessary.

C. General Opposition to the Proposed Rule

Comment: Two commenters said the rule would cause an unnecessary financial obstacle to an already tedious and burdensome process for prospective immigrants. One commenter said that the additional fee would oppress minorities and put unnecessary financial barriers on families and extend the time it takes for them to receive clearance. The commenter explained that the process to become a legalized citizen is already an extensive process and extending it further could turn away families from receiving legalization.

Response: The H–1B classification is an employment-based nonimmigrant classification that allows U.S. employers to temporarily employ foreign workers in specialty occupations. DHS notes that this rule is not addressing the process of obtaining an immigrant visa or lawful permanent resident status. Rather, this rule addresses the fee for filing an H–1B registration which is a prerequisite to being able to file a nonimmigrant petition for a foreign worker in the H–1B nonimmigrant classification. The fee paid for the registration is a responsibility of the petitioning employer, not the foreign worker. DHS believes that a $10 fee for each registration a U.S. employer chooses to submit would not be overly burdensome for employers, especially when considering the benefits of not having to submit a full, paper-based petition as required for possible selection under the current cap selection process. Moreover, the nominal fee would assist DHS in recovering the cost of administering the electronic registration process. Requiring such a fee would not have any impact on the time to adjudicate an immigration benefit request.

D. Establishment of Registration Fee

1. Fee Payment System

Pay.gov

Comments: A few commenters asked DHS to explain with specificity in the final rule how the payment system and payment mechanics will work. The comments related to *pay.gov* are as follows:

- Will DHS utilize *pay.gov* for the payment portal? If an employer is already registered in *pay.gov,* will that registration control for the H–1B registration fee payment?
- Is submission of the registration fee payment via *pay.gov* limited to employers, or may attorneys also submit payments via *pay.gov* on behalf of their U.S. employer clients? The commenter stated that attorneys should be able to submit registration fee payments via the *pay.gov* portal for their U.S. employer clients.
- A professional association stated that, given the limited familiarity of stakeholders with the *pay.gov* portal, USCIS should conduct stakeholder outreach and provide guidance and trainings on how to utilize the *pay.gov* portal well in advance of the initial registration period.

Response: DHS will use *pay.gov* for the payment portal. DHS is using the *pay.gov* architecture to process the payment on the back end, however, petitioners do not need to create a *pay.gov* account to pay the fee. Registrants only have to enter in checking/savings account information to do an ACH (Automated Clearing House) or credit/debit card information to pay via card.[3] G–28 Representatives will be able to pay on *pay.gov* as well, given that there is no need for an account, just basic payment details. USCIS is planning to conduct stakeholder outreach and provide training on how to use the *pay.gov* portal and will announce these trainings on the USCIS website.

Payment Sources

Comments: The comments on payment sources include the following:

- An advocacy group asked if *pay.gov* would allow access to payment via computerized access to bank account and ACH payment systems. This commenter also asked if there would be a one-time registration per user of banking and *pay.gov* information.
- A professional association stated that it appears that the registration fee payment can be paid with either a debit or credit card, or with a withdrawal from a checking or savings account, but USCIS only provides a screen shot in the workflow document for the credit card payment transaction. The commenter urged USCIS to allow for the registration fee to be paid with a withdrawal from a checking or savings account (ACH), as this is a common method of payment and will better accommodate U.S. employers and immigration practitioners submitting registrations on behalf of a high volume registrants.
- A business association asked if there would be an ACH processing fee associated with using this method of payment. If so, the commenter asked if USCIS incorporated those costs into how it factored the $10/registration fee such that it would be covered by the $10 fee or in addition to the $10 fee. If the processing fee is separate from the $10 registration fee, the commenter asked how much these processing fees would add onto the $10 fee.

Response: The registration system will permit payments to be made from a bank account (checking or savings), a credit card, or debit card. No ACH fee will be charged. The registration fee cannot be made using cash, a certified (bank) check, or money order.

Batch Payments

Comments: The comments on batch payments include the following:

- A couple of commenters asked if employers would be able to batch payments for multiple registrations.
- A business association supported the ability of the employer or representative to file registrations for more than one beneficiary under one account, but said the NPRM does not indicate how many registrations a petitioner can file at the same time or exactly how the payment system will operate. Similarly, another commenter asked whether the payment system would limit the amount of beneficiaries that can be batched for simultaneous payment at any given time.
- Another commenter also stated that they support the ability to bundle the H–1B registration fees for multiple registrations into one payment, but said it is unclear whether the *pay.gov* portal would permit a registrant to make several bundled registration fee payments on multiple occasions over a period of several days, or if only one bundled registration fee could be submitted during the registration period. Because large U.S. employers will likely submit registrations throughout the registration period, the commenter recommended that the

[3] Per 8 CFR 103.7(a)(2), remittances must be drawn on a bank or other institution located in the United States and be payable in United States currency.

system should allow registrants to make several bundled registration fee payments through the *pay.gov* portal.

• A business association said the final H–1B Registration Rule stated that employers would not be required to enter their corporate information for each potential beneficiary. The commenter asked if employers would be able to file information regarding the corporation, the authorized employee of the corporation, and the payment method/information used to pay the fees one time throughout this process, and if so, how that would be done.

Response: The registration system will allow for batch payments to pay the fee for multiple registrations submitted simultaneously. For example, one registrant may submit five registrations at one time and make one payment of $50 for the cost of the five registrations. There is no limit to the number of registrations that can be submitted at one time. Registrants would be able to submit as many registrations in as many batches as they see fit during the registration period. For example, a registrant could submit five registrations and pay a $50 fee on March 2, a batch of five registrations on March 5 and pay another $50 fee, and a batch of eight registrations with an $80 fee on March 15.

Registrants will not be required to enter their corporate information for each potential beneficiary. Corporate and payment information will only need to be entered one time for each batch of registrations and associated payments. However, the corporate and payment information will not carry over between subsequent batches of registrations and fees.

Other Comments/Questions on Fee Payment Processing

Comments: Additional comments on fee payment processing are as follows:

• A business association stated that they were concerned about the lack of specificity regarding how the $10 fee will be collected. The commenter wrote that, as USCIS moves to finalize this proposal, the agency should clearly lay out how employers will have to use the H–1B registration's system payment mechanism.

• An advocacy group asked how far in advance of the registration period would registration be permitted for the payment portal.

Response: DHS will use *pay.gov* for the payment portal, however, there is no need to register with *pay.gov* in order to pay for an H–1B registration. The *pay.gov* architecture is used only to process the payments. USCIS will advise registrants of the location of the H–1B registration portal, and any deadlines or other restrictions that will apply. The H–1B registration system will contain clear instructions for completing and submitting registrations and fees.

2. Fee Amount ($10 per Registration)

Comment: Two commenters wrote that the proposed fee was too low without providing an alternative amount. One commenter noted that they were in favor of requiring a fee for H–1B petitions, but that it should be a larger fee. This commenter wrote that a fee free H–1B application and the lower wages paid to those granted H–1B status provides incentive to hire non-U.S. citizens for U.S. based careers. One commenter suggested a $500 fee, while another suggested a $1,000 fee. One commenter said that based upon the assertion that the registration would be a 7-minute additional time burden, the $10 registration fee is appropriate and can be considered a nominal expense for most petitioners.

Response: First, DHS notes that the $10 registration fee is separate from and in addition to the H–1B petition filing fee.[4] The registration fee will be charged regardless of whether the potential petitioner's registration is selected; *i.e.* even if the petitioner may not ultimately file an H–1B petition. As stated in the NPRM, USCIS lacks sufficient data to precisely estimate the costs of the registration process. DHS proposed a $10 fee to provide an initial stream of revenue to mitigate potential fiscal effects on USCIS. Following implementation of the registration fee provided for in this rule, USCIS will gather data on the costs and burdens of administering the registration process in its next biennial fee review to determine whether a fee adjustment is necessary to ensure full cost recovery.

3. Fraud Deterrent

Comment: One commenter asked how the nominal fee will prevent large outsourcing companies from gaming the H–1B system, when their revenue is in the billions. A professional association stated that the addition of a $10 registration fee will not sufficiently deter speculative and/or fraudulent filings. Another commenter noted that requiring employers to pay a more substantial fee may protect employees from predatory employers and that we should include a provision barring employers from passing the fee on to their employees or garnishing it from their wages.

Response: As stated in the proposed rule, the purpose of the registration fee is to recover the costs of the registration system and process; however, the fee may have an added benefit of deterring frivolous registrations. USCIS will monitor the system for potential fraud and abuse (*e.g.* monitoring the system to determine if employers are submitting many registrations but filing petitions based on selected registrations at a significantly lower rate, which could reflect gaming of the system to unfairly improve their odds of being selected). Further, DHS will require registrants to attest that they intend to file an H–1B petition for the beneficiary in the position for which the registration is filed. This attestation is intended to ensure that each registration is connected with a bona fide job offer and, if selected, will result in the filing of an H–1B petition.

In response to a commenter's proposal to bar employers from passing the fee on to the beneficiary (foreign worker), DHS is not adopting this suggestion because it is unnecessary and already prohibited by DOL regulations as an unauthorized deduction. See 20 CFR 655.731(b)(9)(ii) (" . . . except that the deduction may not recoup a business expense(s) of the employer (including attorney fees and other costs connected to the performance of H–1B program functions which are required to be performed by the employer, *e.g.,* preparation and filing of LCA and H–1B petition); . . ."). DHS notes that this prohibition encompasses the costs of an H–1B registration.

Comment: A professional association recommended that, in its calculations for how many registrations will be selected in the registration lottery, USCIS take into consideration that there may be a significantly higher rate of selected registrations resulting in unfiled, denied, or revoked petitions. This commenter also recommended that USCIS reserve enough unselected registrations that could be invited to file in the situation where the H–1B petition approval rate will not result in meeting the H–1B numerical limitations for FY 2021.

[4] As stated in the proposed rule, H–1B petitioners currently pay a $460 filing fee per petition. In addition to the filing fee, certain H–1B petitions may have to pay up to $6,000 in statutory fees. DHS does not have the authority to adjust the amount of these statutory fees. USCIS does not retain most of the revenue. CBP receives 50 percent of the $4,000 9–11 Response and Biometric Entry-Exit fee and the remaining 50 percent is deposited into the General Fund of the Treasury. USCIS retains 5 percent of the $1,500 or $750 American Competitiveness and Workforce Improvement Act (ACWIA) fee. The remainder goes to the Department of Labor and the National Science Foundation. USCIS retains one third of the $500 Fraud Detection and Prevention fee, while the remainder is split between the Department of State and the Department of Labor. *See* 84 FR 46462–46463.

Response: When registration is not required, USCIS randomly selects a certain number of H–1B cap-subject petitions projected as needed to meet the numerical allocations. USCIS makes projections on the number of H–1B cap-subject petitions necessary to meet the numerical limits, taking into account historical data related to approvals, denials, revocations, and other relevant factors.[5] USCIS uses these projections to determine the number of petitions to select to meet, but not exceed, the 65,000 regular cap and 20,000 advanced degree exemption, although the exact percentage and number of petitions may vary depending on the applicable projections for a particular fiscal year. Similarly, in years when USCIS will use the registration system, it will project how many registrations need to be selected in order to meet, but not exceed the numerical limitations. Unselected registrations will remain on reserve for the applicable fiscal year. If USCIS determines that it needs to increase the number of registrations projected to meet the regular cap or advanced degree exemption, and select additional registrations, USCIS would select from among the registrations that are on reserve a sufficient number to meet the cap or advanced degree exemption, or re-open the registration period if additional registrations are needed to meet the new projected amount.

4. Equity of Registration Fee

Comment: A commenter stated that H–1B petitioners have established willingness and ability to pay the nominal H–1B registration fee. The commenter stated a $10 fee is justifiable because the employers are the ones who pay existing H–1B related filing fees rather than investing this money to cultivate the knowledge of existing employees to better their business.

Response: DHS agrees that a $10 fee for each registration will not be overly burdensome for employers and will assist DHS in recovering the cost of administering the registration process.

E. Impact on Small Entities

Comment: Two commenters addressed the proposal's impact on small entities. A business association said USCIS stated that the $10 registration fee might minimize the possibility that larger employers could flood the system crowding out smaller, compliant firms. The commenter said it remains concerned about how the overall H–1B registration system will impact small businesses and urged USCIS to monitor and report on the filings. One commenter said that they were concerned there were not enough safeguards in place to prevent unscrupulous petitioners from flooding the H–1B system. This commenter wrote that DHS should conduct additional outreach consistent with the Regulatory Flexibility Act (RFA), especially to small business entities, so that concerns about potential flooding of the registration system can be addressed prior to implementation.

Response: DHS has already put several safeguards in place to prevent employers from flooding the H–1B registration system, and will monitor the system throughout the registration process. As noted in the H–1B registration final rule, DHS believes it is too speculative to conclude that the H–1B registration system would result in large entities crowding out smaller entities for H–1B prospective employees. With the registration system, and the lower nominal fee, the barrier to entry associated with the registration system could result in increased participation by small entities in the competition for H–1B cap-subject nonimmigrant visas. As noted in the proposed rule, the new fee will impose a nominal compliance cost for any entity, including small entities, that choose to compete for an H–1B cap-subject visa. DHS maintains that the proposed fee will not impose a significant impact on small entities.

F. Paperwork Reduction Act

Comment: A professional association stated that USCIS' estimate of a 7-minute additional time burden for reading the instructions and completing the electronic fee payment was ''extremely low'' and appears to assume that stakeholders are familiar with the *pay.gov* portal, rather than first time users. However, the commenter stated that many U.S. employers and attorneys have little or no experience using the *pay.gov* portal. The commenter wrote that USCIS should recalculate the total public burden (in time) to take into consideration that in many, if not most cases, registrants will be accessing and navigating the *pay.gov* portal for the very first time when submitting initial H–1B registrations.

Response: The *pay.gov* screen will be seamlessly linked to the registration platform and will not require a separate log in, password, or navigation to a separate website. Paying the $10 fee will be very similar to paying for events or airline tickets, merchandise, and other orders placed online, and USCIS anticipates it will be a straightforward process for the public. In addition and as noted above, USCIS intends to conduct outreach and training on how to use the registration system, including making payments on the *pay.gov* portal, and will announce these trainings on the USCIS website. USCIS has received approval from OMB–OIRA to discontinue the approval of this collection of information as guidance found at the website *pra.digital.gov* stated that such payment transactions are not subject to the PRA.

G. Implementation Timeframe

Comment: Two commenters addressed the implementation timeframe for the proposed fee or the H–1B registration process more generally and expressed concern about the lack of a definitive decision from USCIS to implement the new H–1B registration requirement to which the $10 registration fee will be attached. These commenters asked that USCIS notify the public as soon as possible with a final decision on whether usability testing supports proceeding with the registration tool. One commenter stated that, without a final decision and proper notice being provided to stakeholders at this point in time, many business have already begun expending resources in the preparation of various supporting documents for the cap-subject H–1B petitions as they normally would, thus negating the cost savings intended by the rule. One commenter noted that if USCIS does not announce that it will proceed with registration until shortly before the FY2021 cap season begins in April 2020, it will likely be most harmful to the interests of smaller employers who have less overall resources to deal with new regulatory requirements in a short period of time. A few commenters stated that, no later than November 1, 2019, USCIS should publicly announce its decision to implement the registration system in the Spring of 2020 for FY 2021 cap-subject H–1B cases. An advocacy group stated that this notice could be posted on the agency's website or could come with the publication of the H–1B registration fee final rule, so it can be announced in the **Federal Register** months before any registration period would be opened. This commenter also said USCIS should indicate as early as possible the dates when the specific registration period will occur and should consider a registration period longer than the 2-week minimum registration period identified in the final rule.

Response: USCIS intends to implement the registration process for FY 2021, subject to continued testing of the system. DHS will publish a notice in the **Federal Register** to announce the initial implementation of the H–1B

[5] *See* 8 CFR 214.2(h)(8)(ii)(B).

registration process in advance of the cap season in which it will first implement the requirement. USCIS will notify the public about the implementation timeframe of the registration system and the initial registration period as soon as possible, and will provide stakeholders with plenty of notice prior to implementing the registration requirement.

Comment: One commenter asked that as DHS moves to finalize and implement the H–1B registration fee, it continue public outreach on usability testing as a means to further assess the technical details of the registration mechanics. A business association said USCIS should (1) engage stakeholders and fully vet the new platform before instituting the electronic registration system and (2) extend the registration period to at least 30 days to account for any system outages, difficulties in entering data, or other unforeseen problems.

Response: USCIS intends to continue stakeholder outreach and training prior to the initial implementation of the registration system to allow stakeholders the opportunity to familiarize themselves with the electronic registration process. USCIS will provide guidance on how to use the registration system and edit registrations prior to opening the registration system for the initial registration period. DHS will announce the duration of the initial registration period in the **Federal Register** notice.

H. Out of Scope

DHS received many comments that were unrelated to the proposed revisions regarding the registration fee. Many of these comments would require Congressional action or additional regulatory action by DHS unrelated to the H–1B registration fee requirement. Although DHS has summarized the comments it received below, DHS is not providing substantive responses to those comments as they are beyond the scope of this rulemaking. To the extent that comments are seeking further revisions to the H–1B program, DHS recognizes that additional regulatory changes could improve the H–1B program and intends to propose a separate rule to strengthen the H–1B visa classification. As stated in the Unified Agenda of Proposed Regulatory Actions, 83 FR 57803, DHS plans to propose to revise the definition of specialty occupation to increase focus on obtaining the best and the brightest foreign nationals via the H–1B program, and revise the definition of employment and employer-employee relationship to better protect U.S. workers and wages. In addition, DHS will propose additional requirements designed to ensure employers pay appropriate wages to H–1B nonimmigrant workers.

Comments from the public outside the scope of this rulemaking concerned the following issues:

- Some commenters provided suggestions for improvement of the H–1B program in general, including to raise the H–1B salary minimum.
- Some commenters said DHS should review the B–1, [Optional Practical Training] OPT, EB–1, H–4, [Employment Authorization Document] EAD, and L–1/L–2 visa programs to address unfairness, reduce fraud and abuse within the programs, address specific companies known for abuses, and protect wages of American workers.
- One commenter expressed safety concerns that H–1B workers are managing critical infrastructure at state government facilities due to an influx of H–1B workers in the fields of IT, human resources, and contracting.
- Another commenter said H–1B is a ''legalized scam.''

Response: DHS appreciates these suggestions, however, DHS did not propose to address these issues in the proposed rule, therefore these suggestions fall outside of the scope of this rulemaking.

As discussed previously, DHS is finalizing this rule as proposed.

IV. Statutory and Regulatory Requirements

A. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs, benefits, and transfers of available alternatives, and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Information and Regulatory Affairs (OIRA) has not designated this rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, OIRA has not reviewed this rule. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB's Memorandum ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017).

1. Summary

DHS will amend its regulations to require a fee for each registration submitted to register for the H–1B cap selection process. DHS will require a fee of $10 per registration to recover some of the costs that are associated with implementing and maintaining the H–1B cap registration system. USCIS suspended the registration requirement for the FY 2020 H–1B cap selection process. DHS recognizes that the registration requirement was established to provide efficiency savings to both USCIS and H–1B cap-subject petitioners associated with the current paper-based cap selection process. In the H–1B registration final rule, DHS estimated significant cost savings for both USCIS and those H–1B petitioners. DHS stands by that analysis and believes that USCIS will still reap significant efficiency and cost savings when comparing an electronic registration process relative to the current paper filing and cap selection process. DHS acknowledges that the $10 registration fee will reduce some of the estimated cost savings for unselected H–1B cap-subject petitioners as described in the H–1B registration final rule. As discussed in the Regulatory Review section, DHS does not believe that the proposed registration fee will significantly factor into the decision-making of potential H–1B petitioners, nor does DHS believe that the fee will be perceived as being cost-prohibitive by these potential H–1B petitioners. After the registration requirement is implemented and reviewed over the coming years, DHS will consider the costs associated with the system as required during biennial fee reviews and adjust the registration fee accordingly via notice-and-comment rulemaking.

2. Analysis of Costs and Benefits

When registration is required, all petitioners seeking to file an H–1B cap-subject petition, including those eligible for the advanced degree exemption, must first electronically register with USCIS during a designated registration period. A separate registration must be submitted for each worker on whose behalf a petitioner seeks to file an H–1B cap-subject petition. Only those petitioners whose registrations are selected will be eligible to file an H–1B cap-subject petition during an associated filing period for the applicable fiscal year. By means of this rule, DHS will require payment of a $10 registration fee for each registration, which will be due and payable at the time of registration submission. A registration will not be considered as

properly submitted until the fee is paid.[6] In the analysis accompanying the H–1B registration final rule, DHS estimated that 192,918 H–1B cap-subject registrations will be submitted annually based on 5-year historical average Form I–129 petition filings.[7] That estimate will form the baseline for the analysis of costs associated with the $10 registration fee. As DHS acknowledged in the H–1B registration final rule, the use of this historical average to form the baseline estimate does not factor in the possibility that the registration's lower barrier to entry could result in increasing the number of registrations that USCIS receives.[8] To account for this possibility, this analysis will present a range analysis of annual costs up through an escalator of 30 percent increase over the baseline estimate.

Table 1 presents the annual, undiscounted, aggregate costs associated with the $10 registration fee using a range of escalations over the baseline estimate of registrations.

TABLE 1—UNDISCOUNTED AGGREGATE COST ESTIMATES BY PROJECTED REGISTRATIONS

	Number of registrations	Annual cost—undiscounted
Baseline	192,918	$1,929,180
Baseline Plus 10%	212,210	2,122,100
Baseline Plus 20%	231,502	2,315,020
Baseline Plus 30%	250,793	2,507,930

USCIS is required to review the cost of its operations on a biennial basis and recommend fee adjustments as necessary. USCIS may adjust the filing fees for immigration benefits and services through notice-and-comment rulemaking. DHS used a 5-year period of analysis to account for a potential time lag of the fee review and the actual adjustment that occurs during the rulemaking cycle. Therefore, it is reasonable to conclude that a 5-year period is a sufficient period for DHS to base the analysis of the estimated impact of the registration fee.

In addition to the $10 registration fee, USCIS projects there will be an additional 7-minute time burden associated with reading the instructions and completing the electronic fee payment. In the H–1B registration final rule, DHS monetized time burdens based on who is expected to submit the registration: A human resources (HR) specialist; an in-house lawyer; or an outsourced lawyer.[9] The relevant wage is currently $32.11 [10] per hour for an HR specialist and $69.34 [11] per hour for an in-house lawyer. DHS accounts for worker benefits when estimating the opportunity cost of time by calculating a benefits-to-wage multiplier using the Department of Labor, BLS report detailing the average employer costs for employee compensation for all civilian workers in major occupational groups and industries. DHS estimates that the benefits-to-wage multiplier is 1.46 and, therefore, is able to estimate the full opportunity cost per applicant, including employee wages and salaries and the full cost of benefits such as paid leave, insurance, and retirement.[12] DHS multiplied the average hourly U.S. wage rate for HR specialists and lawyers by 1.46 to account for the full cost of employee benefits and overhead, for a total of $46.88 [13] per hour for an HR specialist and $101.24 [14] per hour for an in-house lawyer. DHS recognizes that a firm may choose, but is not required, to outsource the preparation of these registrations and, therefore, has presented two wage rates for lawyers. To determine the full opportunity costs if a firm hired an outsourced lawyer, DHS multiplied the average hourly U.S. wage rate for lawyers by 2.5 for a total of $173.35 [15] to approximate an hourly billing rate for an outsourced lawyer.[16] The monetized equivalent time burden for 7 minutes (0.12 hours) is $5.63,[17] $12.15,[18] and $20.80 [19] for an HR specialist, in-house lawyer, and outsourced lawyer, respectively.

Based on a review of historical filings, USCIS determined that approximately 75 percent of H–1B cap-subject petitions are filed by an attorney or accredited representative.[20] This analysis will carry that finding forward to estimate the time burden costs for complying with the registration fee requirement. In other words, the analysis of time burden costs presented assumes that 25 percent of the registrations will be completed by an HR specialist or representative, and 75 percent of the registrations will be completed by an attorney, either in-house or outsourced. Table 2 presents the annual, undiscounted, time burden or opportunity costs associated with paying the registration fee electronically, assuming 7 minutes of time burden, over a range of estimated numbers of registrations and according to who submits the H–1B registration.

[6] *See* 8 CFR 103.2(a)(1) and 8 CFR 214.2(h)(8)(iii)(A)(*1*).

[7] *See* 84 FR at 925.

[8] *Id.*

[9] *See* 84 FR at 929.

[10] Bureau of Labor Statistics, U.S. Department of Labor, ''Occupational Employment Statistics, May 2018, Human Resources Specialist'': *https://www.bls.gov/oes/2018/may/oes131071.htm.* Visited October 2, 2019.

[11] Bureau of Labor Statistics, U.S. Department of Labor, ''Occupational Employment Statistics, May 2017, Lawyers'': *https://www.bls.gov/oes/2018/may/oes231011.htm.* Visited October 2, 2019.

[12] The benefits-to-wage multiplier is calculated as follows: (Total Employee Compensation per hour)/(Wages and Salaries per hour). *See* Economic News Release, U.S. Dep't of Labor, Bureau of Labor Statistics, Table 1. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Civilian workers, by major occupational and industry group (June 2019), available at *https://www.bls.gov/news.release/archives/ecec_09172019.pdf* (viewed October 2, 2019). The ECEC measures the average cost to employers for wages and salaries and benefits per employee hour worked.

[13] Calculation: $32.11 * 1.46 = $46.88 total wage rate for HR specialist.

[14] Calculation: $69.34 * 1.46 = $101.24 total wage rate for in-house lawyer.

[15] Calculation: $69.34 * 2.5 = $173.35 total wage rate for an outsourced lawyer.

[16] *See* 83 FR at 24914 (May 31, 2018). The DHS analysis in, ''Exercise of Time-Limited Authority To Increase the Fiscal Year 2018 Numerical Limitation for the H–2B Temporary Nonagricultural Worker Program'' used a multiplier of 2.5 to convert in-house attorney wages to the cost of outsourced attorney wages. DHS believes the methodology used in the Final Small Entity Impact Analysis remains sound for using 2.5 as a multiplier for outsourced labor wages in this rule.

[17] Calculation: $46.88 hourly wage rate for HR specialist * 0.12 hours = $5.63.

[18] Calculation: $101.24 hourly wage rate for in-house lawyer * 0.12 hours = $12.15.

[19] Calculation: $173.35 hourly wage rate for outsourced lawyer * 0.12 hours = $20.80.

[20] *See* 84 FR at 925.

TABLE 2—ANNUAL TIME BURDEN COST (UNDISCOUNTED) BY PROJECTED REGISTRATIONS & TYPE OF SUBMITTER, ROUNDED

	Number of registrations	HR specialist [21]	In-house lawyer [22]	Outsourced lawyer [23]
Baseline	192,918	$271,532	$1,757,965	$3,009,521
Baseline Plus 10%	212,210	298,686	1,933,764	3,310,476
Baseline Plus 20%	231,502	325,839	2,109,562	3,611,431
Baseline Plus 30%	250,793	352,991	2,285,351	3,912,371

Note that the cost estimates in Table 2 are overstated because they do not account for the scenario of fewer unique entities submitting registrations for multiple workers. DHS assumes that in those cases, the registration submissions would be done at the same time so the fee payment could be bundled, thus reducing the overall time burden associated with submitting separate payments. The DHS analysis in the H–1B registration final rule found that, on average, each employer submitted five petitions.[24] Thus, the estimate of undiscounted costs in Table 2, which is based on the assumption of one petitioning employer filing one petition, is likely overstated by approximately 80 percent. Estimates that are more likely to reflect the current business behavior of five petitions per employer, are presented in Table 3.

TABLE 3—ANNUAL TIME BURDEN COST (UNDISCOUNTED) BY PROJECTED REGISTRATIONS & TYPE OF SUBMITTER, LESS 80%

	Number of registrations	HR specialist	In-house lawyer	Outsourced lawyer
Baseline	192,918	$54,306	$351,593	$601,904
Baseline Plus 10%	212,210	59,737	386,753	662,095
Baseline Plus 20%	231,502	65,168	421,912	722,286
Baseline Plus 30%	250,793	70,598	457,070	782,474

Therefore, the total, undiscounted, aggregate annual costs of both the registration fee and time burden costs are presented in Table 4. The figures in Table 4 are found by adding the proportional costs presented in Table 1 (in other words, assume 25 percent of registrations are completed by HR specialist and 75 percent of registrations are completed by lawyers either in-house or outsourced) with the estimated costs for entities submitting registrations in Table 3.

TABLE 4—AGGREGATE COST (UNDISCOUNTED) BY PROJECTED REGISTRATIONS & TYPE OF SUBMITTER

	Number of registrations	HR specialist (table 3 + 25% of table 1)	In-house lawyer (table 3 + 75% of table 1)	Outsourced lawyer (table 3 + 75% of table 1)
Baseline	192,918	$536,601	$1,798,478	$2,048,789
Baseline Plus 10%	212,210	590,262	1,978,328	2,253,670
Baseline Plus 20%	231,502	643,923	2,158,177	2,458,551
Baseline Plus 30%	250,793	697,581	2,338,018	2,663,422

The lower bound aggregate cost estimate of complying with the registration fee requirement is found by summing the estimated cost of using an HR specialist with the cost estimate of using in-house lawyers to complete the registration. The upper bound aggregate cost estimate is found by summing the estimated cost of using an HR specialist with the cost estimate of using outsourced lawyers to complete the registration. Table 5 presents the lower bound and upper bound aggregate cost estimates over the projected number of registrations for a 5-year period, discounted at 3 and 7 percent.

[21] Calculation: Number of Registrations * 25 percent * $5.63 (figures presented in the table are rounded to the nearest dollar).

[22] Calculation: Number of Registrations * 75 percent * $12.15 (figures presented in the table are rounded to the nearest dollar).

[23] Calculation: Number of Registrations * 75 percent * $20.80 (figures presented in the table are rounded to the nearest dollar).

[24] *See* 84 FR at 948 (January 31, 2019) for the FY 2016 cohort of H–1B cap-subject petitions selected. Of the 95,839 petitions selected, there were only 20,046 unique entities that filed those petitions. Calculation: 95,839/20,046 = 4.78.

TABLE 5—AGGREGATE COST ESTIMATES BY PROJECTED REGISTRATIONS OVER 5-YEAR PERIOD, DISCOUNTED AT 3% AND 7%

	Number of registrations	5-Year discounted costs, 3%, ($ millions)		5-Year discounted costs, 7%, ($ millions)	
		Lower bound	Upper bound	Lower bound	Upper bound
Baseline	192,918	$10.7	$11.8	$9.6	$10.6
Baseline Plus 10%	212,210	11.8	13.0	105.0	11.7
Baseline Plus 20%	231,502	12.8	14.2	11.5	12.7
Baseline Plus 30%	250,793	13.9	15.4	12.4	13.8

As discussed previously, while this initial registration fee of $10 per registration may not recover the full costs associated with implementing and maintaining the H–1B registration system, it would allow for USCIS to recover some of the costs, thus lessening the fiscal impact to USCIS. DHS does not anticipate the required registration fee to represent a significant business expense for those employers that seek to employ cap-subject H–1B workers. The total costs for each registration would range from $15.63 to $30.80 for a registration, depending on who the petitioner uses to submit the registration. Even with the addition of the registration fee requirement, as discussed previously in the preamble, the registration process is still anticipated to result in a net benefit relative to the paper-based cap selection process.

The registration fee may also provide some unquantified benefits to the extent that the fee may help to deter frivolous registrations. DHS makes no conclusions on the impact that a $10 fee would have on the number of registrations and has no way to estimate such an impact. As stated in the H–1B registration final rule, however, commenters on the H–1B registration proposed rule expressed various concerns about potential ''flooding'' of the registration system. While there is no way to estimate if a small fee would further deter such acts, beyond the measures identified in the H–1B registration final rule (*e.g.,* the attestation requirement), DHS believes that it is reasonable to conclude that the existence of a $10 fee could reduce the likelihood that frivolous registrations would be submitted to flood or otherwise game the registration system. In any event, such a benefit would only be tangential to the fee's primary purpose of recovering USCIS costs.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (March 29, 1996), requires Federal agencies to consider the potential impact of regulations on small entities during the development of their rules. The term ''small entities'' comprises of small businesses, not-for-profit organizations that are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. An ''individual'' is not defined by the RFA as a small entity and costs to an individual from a rule are not considered for RFA purposes. In addition, the courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities. Consequently, any indirect impacts from a rule to a small entity are not considered as costs for RFA purposes.

In the proposed rule, DHS provided a factual basis in certifying the registration fee requirement would not pose a significant impact on small entities for public comment. DHS received no challenges to the certification statement under the RFA, nor to the factual basis presented in support of said certification. DHS is reproducing the factual basis, with updates to correct costs estimates due to calculation errors, in certifying this final rule will not pose a significant impact on small entities.

This final rule will directly impact those entities that petition on behalf of H–1B cap-subject workers. Generally, H–1B petitions are filed by a sponsoring employer; by proxy, once the online registration requirement is implemented, registrations would likewise be submitted by a sponsoring employer or their authorized representative. The employer intending to petition for an H–1B cap-subject worker will incur the registration fee costs of $10 per registration. Therefore, DHS examines the direct impact of this final rule on small entities in the analysis that follows.

In the H–1B registration final rule, DHS estimated that approximately 78 percent of selected H–1B petitioners were small entities after conducting an analysis of a statistically significant sample.[25] DHS believes it is reasonable to carry this finding through and assume that approximately 78 percent, a majority, of H–1B registrations would be submitted by small entities. Thus, for purposes of the RFA, this final rule is expected to impact a ''substantial'' number of small entities.

To determine whether the impact of the required registration filing fee would be ''significant,'' DHS must consider the estimated fee impacts of individual petitioning small entities. In the H–1B registration final rule, DHS found that the majority of petitioning employers tended to submit petitions for multiple employees. Based on a review of filings received in 2016, DHS determined that for every one unique petitioning employer, there were an average of 4.78 petitions submitted.[26] For purposes of this analysis, DHS is rounding that figure up to form a baseline assumption that for every one petitioning employer, a total of five H–1B cap-subject workers are requested. Therefore, it is reasonable to conclude that on average each petitioning employer that is a small entity will face a total fee impact of $50, plus a one-time monetized time burden impact ranging from $5.63 to $20.80, as a result of the required H–1B registration fee.[27]

In that same statistically valid sample study, DHS was able to determine the top 10 industries that petitioned for cap-subject H–1B workers.[28] The industry data, using the North American Industry Classification System (NAICS), is self-reported on USCIS Form I–129, Petition for Nonimmigrant Worker, which petitioning employers use to petition for H–1B workers. Table 6 shows a list of the top 10 NAICS industries that

[25] *See* 84 FR at 948–49.

[26] *See* 84 FR at 948, explaining that, for the FY 2016 cohort, 20,046 unique entities filed the 95,839 H–1B cap-subject petitions that were selected. Calculation: 95,839/20,046 = 4.78.

[27] Calculation: $10 (registration fee) × 5 registrations (one for each H–1B worker being entered into the registration) = $50 total fee impact for employers.

[28] *See* 84 FR at 950.

submitted H–1B cap-subject petitions in the sample study, and the corresponding size standard according to the SBA.

TABLE 6—TOP 10 NAICS INDUSTRIES SUBMITTING FORM I–129, SMALL ENTITY ANALYSIS RESULTS

Rank	NAICS code	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
1	541511	Custom Computer Programming Services	$27.5	
2	541512	Computer Systems Design Services	27.5	
3	561499	All Other Business Support Services	15.0	
4	541330	Engineering Services	15.0	
5	511210	Software Publishers	38.5	
6	541611	Administrative Management and General Management Consulting Services	15.0	
7	334413	Semiconductor and Related Device Manufacturing		1,250
8	541618	Other Management Consulting Services	15.0	
9	541690	Other Scientific and Technical Consulting Services	15.0	
10	325412	Pharmaceutical Preparation Manufacturing		1,250

Source: USCIS analysis based on small business size standards.
Note: The Small Business Administration (SBA) has developed size standards to carry out the purposes of the Small Business Act and those size standards can be found in 13 CFR, section 121.201.

SBA's monetary size standard is based on the average annual receipts of the business entity. As discussed previously, DHS has determined that the majority of H–1B petitioning employers would be classified as ''small'' for purposes of the RFA. However, comparing the expected total fee impact of $55.63 on the low-end for every small entity (assuming each entity submits approximately five registrations) results in a negligible cost impact relative to average annual receipts. In fact, for a cost of $55.63, a company would need to have annual receipts of only $5,563 for the cost of the registration fee for five registrations to equal 1 percent of the annual receipts. If a company used an outsourced lawyer to petition for a visa at a cost of $70.80 (assuming each entity uses an outsourced attorney to submit five registrations) the company would need to have annual receipts of only $7,080 for the cost of the fee to equal 1 percent of the annual receipts.

SBA guidance on additional measures to determine whether a rule would have a significant impact suggest comparing the compliance cost to the labor costs.[29] In that guidance, SBA states that an impact could be significant if the compliance cost ''exceeds 5 percent of the labor costs of the entities in that sector.'' [30] In the annual report to Congress on the characteristics of H–1B workers for fiscal year 2017, USCIS determined the median annual compensation for initial employment across all occupations was $75,000.[31] Furthermore, the median annual compensation for initial employment across known occupations ranged from a low of $42,000 to a high of $160,000.[32] This final rule is estimated to result in compliance costs that represent much less than 5 percent of the H–1B labor costs.

Based on these findings, DHS certifies that while this final rule could impact a substantial number of small entities, the impact that would arise from the $10 registration fee would not result in a significant impact. Therefore, the Secretary certifies that this final rule will not cause a significant impact to a substantial number of small entities.

C. Other Regulatory Requirements

This final rule is not a ''major rule'' as defined by the Congressional Review Act, 5 U.S.C. 804(2), and thus is not subject to a 60-day delay in the rule becoming effective. This action is not subject to the written statement requirements of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 13132 or 13175. This final rule also does not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(2)(ii) and 1508.4. This action would not affect the quality of the human environment and fits within Categorical Exclusion number A3(d) in Dir. 023–01 Rev. 01, Appendix A, Table 1, for rules that interpret or amend an existing regulation without changing its environmental effect.

D. Paperwork Reduction Act

DHS is submitting the information collection requirements in this rule to OMB for review and approval in accordance with requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3512. DHS and USCIS are revising this information collection to report a change in the estimated annual cost to the Federal government as a result of this final rule. Additionally, the information collection instrument has been revised to include language about the new registration fee. The notice of proposed rulemaking stated that DHS proposed a revision to the USCIS Electronic Fee Payment Processing information collection, former OMB Control Number 1651–0131. DHS and USCIS have determined that the collection of information related to fee payment processing is exempt from the Paperwork Reduction Act and that collection of information is not required to be included in this rulemaking.[33] DHS is revising the following USCIS information collection:

H–1B Registration Tool

DHS and USCIS are revising this information collection to report a change in the estimated annual cost to the Federal government as a result of this rule. Additionally, the information collection instrument has been revised to include language about the new registration fee.

[29] *See* U.S. Small Business Administration, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,* The RFA threshold analysis: Can we certify? at Pg. 19, *https://www.sba.gov/sites/default/files/advocacy/How-to-Comply-with-the-RFA-WEB.pdf.* Visited Apr. 16, 2019.

[30] *Id.*

[31] *See* U.S. Citizenship and Immigration Services, *Characteristics of H–1B Specialty Occupation Workers, Fiscal Year 2017 Annual Report to Congress,* at Table 11, *https://www.uscis.gov/sites/default/files/reports-studies/Characteristics-of-Specialty-Occupation-Workers-H-1B-Fiscal-Year-2017.pdf.* Visited Apr. 16, 2019.

[32] *Id.*

[33] See *https://pra.digital.gov/do-I-need-clearance/* Stating, ''Doesn't need PRA Clearance: Information for voluntary commercial transactions, like payment and delivery details.'')

Overview of information collection:

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* H–1B Registration Tool.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Agency Form Number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. USCIS uses the data collected on this form to determine which employers will be informed that they are eligible to submit a USCIS Form I–129, Petition for a Nonimmigrant Worker, to petition for a cap-subject beneficiary in the H–1B classification.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection H–1B Registration Tool is 192,918 and the estimated hour burden per response is 0.5 hours. Any additional time burden for fee payment processing is captured in the information collection USCIS Electronic Fee Payment Processing (OMB 1615–0131).

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 96,459 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total cost burden for purchases of equipment or services to achieve compliance with the information collection requirements of this rule (not including providing information to or keeping records for the government, or kept as part of customary and usual business or private practices), are $0.[34] There are no capital, start-up, operational or maintenance costs to respondents associated with this collection of information.

List of Subjects in 8 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of information, Immigration, Privacy, Reporting and recordkeeping requirements.

Accordingly, DHS is amending chapter I of title 8 of the Code of Federal Regulations as follows:

[34] As stated elsewhere in this rule, the annual transfer for registrants associated with the proposed $10 fee is $1,929,180.

PART 103—IMMIGRATION BENEFITS; BIOMETRIC REQUIREMENTS; AVAILABILITY OF RECORDS

■ 1. The authority citation for part 103 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356, 1356b, 1372; 31 U.S.C. 9701; Pub. L. 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*); E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p. 166; 8 CFR part 2; Pub. L. 112–54, 125 Stat 550.

■ 2. Section 103.7 is amended by adding paragraph (b)(1)(i)(NNN) to read as follows:

§ 103.7 Fees.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(NNN) *Registration requirement for petitioners seeking to file H–1B petitions on behalf of cap-subject aliens.* For each registration submitted to register for the H–1B cap or advanced degree exemption selection process: $10. This fee will not be refunded if the registration is not selected or is withdrawn.

* * * * *

Kevin K. McAleenan,

Acting Secretary.

[FR Doc. 2019–24292 Filed 11–7–19; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 217

RIN 1601–AA94

Designation of Poland for the Visa Waiver Program

AGENCY: Office of the Secretary, Department of Homeland Security (DHS).

ACTION: Final rule; technical amendment.

SUMMARY: Eligible citizens, nationals, and passport holders from designated Visa Waiver Program countries may apply for admission to the United States at U.S. ports of entry as nonimmigrant aliens for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements. On October 31, 2019, the Secretary of Homeland Security, in consultation with the Secretary of State, designated Poland as a country that is eligible to participate in the Visa Waiver Program. Accordingly, this rule updates the list of countries designated for participation in the Visa Waiver Program by adding Poland.

DATES: This final rule is effective on November 11, 2019.

FOR FURTHER INFORMATION CONTACT: Erik Rye, Department of Homeland Security, Visa Waiver Program Office, (202) 282–9907.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Visa Waiver Program

Pursuant to section 217 of the Immigration and Nationality Act (INA), 8 U.S.C. 1187, the Secretary of Homeland Security (the Secretary), in consultation with the Secretary of State, may designate certain countries as Visa Waiver Program (VWP) countries [1] if certain requirements are met. Those requirements include, without limitation: (1) A U.S. Government determination that the country meets the applicable statutory requirement with respect to nonimmigrant visitor visa refusals for nationals of the country; (2) an official certification that it issues machine-readable, electronic passports that comply with internationally accepted standards; (3) a U.S. Government determination that the country's designation would not negatively affect U.S. law enforcement and security interests; (4) an agreement with the United States to report, or make available through other designated means, to the U.S. Government information about the theft or loss of passports; (5) a U.S. Government determination that the government accepts for repatriation any citizen, former citizen, or national not later than three weeks after the issuance of a final executable order of removal; and (6) an agreement with the United States to share information regarding whether citizens or nationals of the country represent a threat to the security or welfare of the United States or its citizens.

The INA also sets forth requirements for continued eligibility and, where appropriate, probation and/or termination of program countries.

[1] All references to ''country'' or ''countries'' in the laws authorizing the Visa Waiver Program are read to include Taiwan. *See* Taiwan Relations Act of 1979, Public Law 96–8, section 4(b)(1) (codified at 22 U.S.C. 3303(b)(1)) (providing that ''[w]henever the laws of the United States refer or relate to foreign countries, nations, states, governments, or similar entities, such terms shall include and such laws shall apply with respect to Taiwan''). This is consistent with the United States' one-China policy, under which the United States has maintained unofficial relations with Taiwan since 1979.

Prior to this final rule, the designated countries in the VWP were Andorra, Australia, Austria, Belgium, Brunei, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New Zealand, Norway, Portugal, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan,[2] and the United Kingdom.[3] *See* 8 CFR 217.2(a).

Citizens and eligible nationals of VWP countries may apply for admission to the United States at U.S. ports of entry as nonimmigrant visitors for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements. To travel to the United States under the VWP, an alien must satisfy the following:

(1) Be seeking admission as a nonimmigrant visitor for business or pleasure for ninety days or less;

(2) be a national of a program country;

(3) present a machine-readable, electronic passport issued by a designated VWP participant country to the air or vessel carrier before departure;

(4) execute the required immigration forms;

(5) if arriving by air or sea, arrive on an authorized carrier;

(6) not represent a threat to the welfare, health, safety, or security of the United States;

(7) have not violated U.S. immigration law during any previous admission under the VWP;

(8) possess a round-trip ticket, unless exempted by statute or federal regulation;

(9) the identity of the alien has been checked to uncover any grounds on which the alien may be inadmissible to the United States, and no such ground has been found;

(10) certain aircraft operators, as provided by statute and regulation, must electronically transmit information about the alien passenger;

(11) has not been present at any time after March 1, 2011 in Iraq, Syria, or any other country so designated by statute and regulation;

(12) waive the right to review or appeal a decision regarding admissibility or to contest, other than on the basis of an application for asylum, any action for removal; and

(13) obtain an approved travel authorization via the Electronic System for Travel Authorization (ESTA). For more information about the ESTA, please see 8 CFR 217.5 (regulation effective July 8, 2015), 80 FR 32267 (June 8, 2015), 75 FR 47701 (Aug. 9, 2010).

See sections 217(a) and 217(b) of the Immigration and Nationality Act (INA), 8 U.S.C. 1187(a)–(b); *see also* 8 CFR part 217.

B. Designation of Poland

The Department of Homeland Security, in consultation with the Department of State, has evaluated Poland for VWP designation to ensure that it meets the requirements set forth in section 217 of the INA, as amended by section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110–53. The Secretary has determined that Poland has satisfied the statutory requirements for initial VWP designation; therefore, the Secretary, in consultation with the Secretary of State, has designated Poland as a program country.[4]

This final rule adds Poland to the list of countries authorized to participate in the VWP. Accordingly, beginning November 11, 2019, eligible citizens and nationals of Poland may apply for admission to the United States at U.S. ports of entry as nonimmigrant visitors for business or pleasure for a period of ninety days or less without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements.

II. Statutory and Regulatory Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The final rule merely lists a country that the Secretary of Homeland Security, in consultation with the Secretary of State, has designated as a VWP eligible country in accordance with section 217(c) of the INA, 8 U.S.C. 1187(c). This amendment is a technical change to merely update the list of VWP countries. Therefore, notice and comment for this rule is unnecessary and contrary to the public interest because the rule has no substantive impact, is technical in nature, and relates only to management, organization, procedure, and practice. For the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

This final rule is also excluded from the rulemaking provisions of 5 U.S.C. 553 as a foreign affairs function of the United States because it advances the President's foreign policy goals and directly involves relationships between the United States and its alien visitors. Accordingly, DHS is not required to provide public notice and an opportunity to comment before implementing the requirements under this final rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 603(b)), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required ''to publish a general notice of proposed rulemaking for any proposed rule.'' Because this rule is being issued as a final rule, on the grounds set forth above, a regulatory flexibility analysis is not required under the RFA.

DHS has considered the impact of this rule on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The individual aliens to whom this rule applies are not small entities as that term is defined in 5 U.S.C. 601(6). Accordingly, there is no change expected in any process as a result of this rule that would have a direct effect, either positive or negative, on a small entity.

C. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

[2] Taiwan refers only to individuals who have unrestricted right of permanent abode on Taiwan and are in possession of an electronic passport bearing a personal identification (household registration) number.

[3] The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands, and the Isle of Man); it does not refer to British overseas citizens, British dependent territories' citizens, or citizens of British Commonwealth countries.

[4] The Secretary of State nominated Poland for participation in the VWP on October 3, 2019.

D. Executive Order 12866

This amendment does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

E. Executive Order 13132

The 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, in accordance with section 6 of Executive Order 13132, DHS has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

The Department of Homeland Security is modifying OMB Control Number 1651–0111, Arrival and Departure Record, to allow eligible Poland passport holders to use the Electronic System for Travel Authorization (ESTA) to apply for authorization to travel under the VWP prior to departing for the United States. CBP uses the information to assist in determining if an applicant is eligible for travel under the VWP. The Department is requesting emergency processing of this change to 1651–0111 as the information is essential to the mission of the agency and is needed prior to the expiration of time periods established under the PRA. Because of the designation of Poland for participation in the VWP, the Department is requesting OMB approval of this information collection in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

The addition of Poland to the Visa Waiver Program will result in an estimated annual increase to information collection 1651–0111 of 300,000 responses and 75,000 burden hours. The total burden hours for ESTA, including Poland, is as follows:

Estimated annual reporting burden: 3,625,000 hours.

Estimated number of respondents: 14,500,000 respondents.

Estimated average annual burden per respondent: 15 minutes.

List of Subjects in 8 CFR Part 217

Air carriers, Aliens, Maritime carriers, Passports and visas.

Amendments to the Regulations

For the reasons stated in the preamble, DHS amends part 217 of title 8 of the Code of Federal Regulations (8 CFR part 217) as set forth below.

PART 217—VISA WAIVER PROGRAM

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

Authority: 8 U.S.C. 1103, 1187; 8 CFR part 2.

■ 2. In § 217.2(a), the definition of ''Designated country'' is revised to read as follows:

§ 217.2 Eligibility.

(a) * * *

Designated country refers to Andorra, Australia, Austria, Belgium, Brunei, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands, and the Isle of Man); it does not refer to British overseas citizens, British dependent territories' citizens, or citizens of British Commonwealth countries. Taiwan refers only to individuals who have unrestricted right of permanent abode on Taiwan and are in possession of an electronic passport bearing a personal identification (household registration) number.

* * * * *

Kevin McAleenan,

Acting Secretary.

[FR Doc. 2019–24328 Filed 11–7–19; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. FSIS–2016–0002]

RIN [0583–AD64]

Eligibility of the People's Republic of China (PRC) To Export to the United States Poultry Products From Birds Slaughtered in the PRC

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to add the People's Republic of China (PRC) as eligible to export to the United States poultry products from birds slaughtered in the PRC. FSIS has reviewed the PRC's poultry laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the United States' food safety system for poultry. Under this final rule, slaughtered poultry, or parts or other products thereof, processed in certified PRC establishments, are eligible for export to the United States. All such products are subject to reinspection at United States ports of entry by FSIS inspectors.

DATES: Effective December 9, 2019.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–3700; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On June 16, 2017, FSIS published a proposed rule in the **Federal Register** (82 FR 27625) to amend FSIS's poultry products inspection regulations to list the PRC as eligible to export to the United States poultry products from birds slaughtered in the PRC. FSIS proposed this action after the Agency conducted a documentary review of the PRC's laws, regulations, and poultry slaughter inspection system, as well as an in-country audit of the system, and determined that it is equivalent to the U.S. system established under the Poultry Products Inspection Act (PPIA) and its implementing regulations. This final rule is consistent with the provisions of the proposed rule.

The PRC is already eligible to export processed poultry products to the United States if the products are derived from poultry slaughtered in the United States or in other countries with a poultry slaughter inspection system equivalent to that of the United States. Under this final rule, the PRC is eligible to export to the United States poultry products derived from birds slaughtered in the PRC. The PRC may not export raw poultry at this time because of restrictions owing to animal disease risk put in place by the USDA Animal and

Plant Health Inspection Service (APHIS). Regarding processed poultry, the PRC may only export Fully Cooked-Not Shelf Stable products, because FSIS has only assessed information and audited the government controls for the production of products under this processing category.[1] The PRC would need to submit additional information for FSIS to review, and would likely need to undergo an additional audit before FSIS would allow the PRC to export other processed poultry products to the United States.

As explained in the proposed rule, under the PPIA and implementing regulations, poultry and poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling that are equivalent to those of the U.S. system (21 U.S.C. 466). Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry and poultry products to the United States.

Paragraph 381.196(a) requires that the standards of a foreign country's poultry inspection system, its legal authority for the inspection system, and the regulations implementing the system must be equivalent to those of the United States. These requirements include: (1) Ante-mortem and post-mortem inspection performed or supervised by a veterinarian; (2) national government controls over establishment construction, facilities, and equipment; (3) verification of slaughtering of poultry and processing of poultry products by inspectors to ensure that product is not adulterated or misbranded; (4) separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at certified establishments; (7) controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements under the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

The country's inspection program must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing in certified establishments to ensure uniform enforcement of laws and regulations; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements (9 CFR 381.196(a)(2)(i)).

Evaluation of the PRC's Poultry Inspection System

In 2004, at the request of the PRC, FSIS conducted a document review of the PRC's poultry (slaughter and processing) inspection system, concluding that the PRC's laws, regulations, control programs, and procedures were equivalent to those of the United States. FSIS proceeded with an on-site audit to verify that the PRC's General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ), which was the PRC's central competent authority (CCA) in charge of food inspection, had effectively implemented a poultry inspection system equivalent to that of the United States.[2] However, FSIS identified problems involving sanitation, slaughter, processing, residue controls, supervision, and enforcement. In 2005, FSIS conducted a follow-up on-site audit and concluded that the PRC had satisfactorily addressed the previous audit findings for poultry processing only.

In 2006, FSIS published a final rule in the **Federal Register** making the PRC eligible to export poultry products to the United States, but only from birds slaughtered under Federal inspection in the United States or other countries eligible to export slaughtered poultry products to the United States (71 FR 20867, April 24, 2006). Shortly after the publication, Congress prohibited FSIS from allowing poultry products to be imported from the PRC (see Sec. 733 of Pub. L. 110–161). In 2009, Congress removed this prohibition.

In June 2010, FSIS experts traveled to the PRC to collect information related to legislation applicable to the country's poultry inspection system, including the PRC's 2009 Food Safety Law. In December 2010, FSIS conducted separate but concurrent on-site audits of the PRC's poultry slaughter and processing inspection systems. FSIS reviewed the effectiveness of the PRC's food safety program based on whether the following equivalence components were addressed satisfactorily with respect to standards, activities, resources, and enforcement: (1) Government Oversight (*e.g.,* Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (*e.g.,* Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government HACCP Systems; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The auditors concluded that the PRC was able to meet the principal requirements for the equivalence components of Government Sanitation and Government Chemical Residue Programs. However, FSIS identified systemic inadequacies in both the slaughter and processed poultry inspection systems regarding the other four equivalence components. For example, FSIS found that the CCA lacked a standardized method to assign inspection personnel to slaughter facilities and also utilized establishment-paid inspectors to conduct official inspection duties. The CCA responded by developing a comprehensive corrective action plan addressing the findings.

In March 2013, FSIS conducted follow-up on-site audits to verify whether the PRC had implemented the corrective actions proffered in response to the previous audit findings. Based on the audit findings, FSIS concluded that the PRC's processed poultry inspection system was equivalent to the U.S. system and announced that the PRC could export processed poultry products to the United States. However, FSIS also found that the CCA had not adequately addressed all of FSIS's concerns about its poultry slaughter inspection system. Specially, the CCA still lacked a standardized method to assign inspection personnel to slaughter facilities on the basis of objective measurements. The CCA responded to these concerns, stating that it would implement changes to its poultry slaughter inspection system.

In May 2015, FSIS conducted an on-site audit to verify whether the CCA adopted the necessary corrective measures to its poultry slaughter inspection system. Based on the audit, FSIS concluded that the PRC had satisfactorily addressed all issues of concern that FSIS had raised in its 2013 audit of the PRC poultry slaughter

[1] See FSIS Product Categorization guide, available at: *https://www.fsis.usda.gov/wps/wcm/connect/abbf595d-7fc7-4170-b7be-37f812882388/Product-Categorization.pdf?MOD=AJPERES.*

[2] Since FSIS completed its preliminary determination regarding equivalence of the PRC's poultry inspection system, the PRC has reorganized and renamed its CCA, now organized under the General Administration of Customs of the People's Republic of China. This reorganization has no substantive impact on FSIS' determination of equivalence.

inspection system and had met the FSIS equivalence criteria for all six components.

On August 21, 2014, FSIS published the final rule *Modernization of Poultry Slaughter Inspection* (79 FR 49566). The rule created regulatory changes that apply to all poultry slaughter establishments and established a new optional post-mortem inspection system, the New Poultry Inspection System (NPIS). On August 11, 2016, the PRC sent a letter to FSIS outlining the changes that were made to the PRC's poultry inspection system to achieve equivalency with the new U.S. regulations. These included requirements that establishments have procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and prerequisite programs to prevent contamination of carcasses and parts by enteric pathogens and visible fecal material. The PRC also stated in the letter that it had adopted the U.S. requirements for NPIS. On September 1, 2016, the PRC sent copies of its updated inspection manuals to FSIS. The letter and the relevant portions of the inspection manuals are available at: *www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules.* FSIS reviewed the submitted letter and updated manuals and determined that the PRC's poultry slaughter inspection system is equivalent to the U.S. system in regard to the *Modernization of Poultry Slaughter Inspection* requirements.

Consequently, on June 16, 2017, FSIS published a proposal to find that the PRC's poultry slaughter inspection system is equivalent to the United States' system and, therefore, to remove from the regulations the limitation that the products must originate from birds slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry products to the United States. For more detailed information on FSIS's evaluations of the PRC's poultry inspection system see the proposed rule (82 FR 27625) and for the full audit reports, go to: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.*

In November 2018, FSIS conducted an audit of PRC's poultry inspection system, reviewing the inspection and regulation by the PRC of both poultry processing and slaughter. FSIS identified no significant problems and the PRC poultry inspection system was again found to be equivalent. FSIS will publish the findings from this audit in the future.

Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS concludes that the PRC's poultry inspection system is equivalent to the United States' inspection system for poultry and poultry products. Therefore, FSIS is amending its poultry products inspection regulations to permit imports from the PRC of poultry products, derived from birds slaughtered in the PRC (9 CFR 381.196(b)). Under FSIS's import regulations, the PRC must certify to FSIS that those establishments that wish to export poultry product to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export poultry products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States, including those of APHIS. These requirements include restrictions under 9 CFR part 94 of APHIS's regulations, which regulate the export of poultry products from foreign countries to the United States to control the spread of specific animal diseases.

Also, under this final rule, all poultry and poultry products exported to the United States from the PRC will be subject to reinspection by FSIS at United States ports of entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. FSIS also will conduct other types of reinspection activities, such as sampling and testing product to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import reinspection activities can be found on the FSIS website at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures.*

Under current congressional appropriations,[3] poultry products permitted for importation under this final rule may not be used in the school lunch program under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*), the Child and Adult Care Food Program under section 17 of such Act (42 U.S.C. 1766), the Summer Food Service Program for Children under section 13 of such Act (42 U.S.C. 1761), or the school breakfast program under the Child Nutrition Act of 1966 (42 U.S.C. 1771 *et seq.*). In addition, poultry products from birds slaughtered in the PRC will be eligible for importation into the United States only if they are from animals slaughtered on or after the effective date of this final rule.

Finally, within one year of the effective date of this final rule, FSIS will conduct an ongoing equivalence audit of the PRC's poultry inspection system. During the audit, FSIS auditors will verify that the PRC's CCA has implemented its food safety inspection system as described in the Self-Reporting Tool and supporting documentation. FSIS auditors will visit government offices, establishments, and laboratories to verify that the CCA has implemented its inspection system as documented and verify that the country's system of controls remains equivalent to the U.S. inspection system. FSIS will be conducting such audits for all newly equivalent countries within one year of the effective date of the final rules granting equivalence. This policy results from an Agency response to a September 2017 audit of FSIS equivalence processes by the USDA Office of Inspector General (*Evaluation of Food Safety and Inspection Service's Equivalency Assessments of Exporting Countries: Audit Report 24601–0002–21*).

Summary of Comments and Responses

FSIS received 96 comments from trade associations representing meat and poultry processors, consumer interest groups, a foodborne illness research center, a large food-processing corporation, and individual consumers. Comments from the meat and poultry industry and two individual consumers supported the proposed rule. Comments from the consumer interest groups and most individual consumers opposed the proposal. The following is a brief summary of the relevant issues raised in the comments and FSIS's responses.

[3] See Section 749, Consolidated Appropriations Act, 2019, Public Law 116–6, enacted February 15, 2019.

Comment: Two consumer interest groups and many individual consumers opposed the rule because of reported outbreaks of avian influenza in the PRC. A consumer interest group stated that even if cooking killed the avian influenza virus, consumers should not have to consume poultry from birds that were sick.

Response: To export poultry products to the United States, countries need to meet APHIS requirements for animal disease prevention and control. APHIS uses several methods to ensure that harmful animal diseases do not enter the United States. These include actively monitoring the animal disease status of foreign countries and maintaining lists of countries and regions considered to be free (or not free) of certain diseases. If an animal disease is found to exist in a country (or a region within a country) that exports meat, poultry, or egg products to the United States, APHIS requires specific processing steps to ensure that any product from that country or region will not cause the disease to be transmitted to the United States (see 9 CFR part 94).

In addition to these monitoring and processing provisions, APHIS requires imported meat, poultry, and egg products to have accompanying documentation regarding their origin, animal disease status, degree of processing, and intended use. At the U.S. border, Customs and Border Protection (CBP) officials verify that such documentation is accurate and that the products do not pose an animal disease transmission risk. These steps take place before FSIS reinspects imported product for food safety and other regulatory compliance. All meat and poultry products that APHIS restricts from entering the United States because of animal disease concerns will be refused entry by CBP.

As FSIS explained in the proposed rule, APHIS has classified China as a region where highly pathogenic avian influenza (HPAI) exists. APHIS also does *not* currently list the PRC as a region free of Exotic Newcastle Disease. Therefore, before a shipment of poultry products may be presented for FSIS reinspection at the port of entry, it must have been processed in a manner sufficient to inactivate these viruses if they were present in the meat, in accordance with APHIS requirements at 9 CFR 94.6. FSIS reinspection of this imported poultry, in addition to the equivalent PRC inspection system, ensures that the product is otherwise safe, wholesome, and unadulterated.

Any poultry intended for export to the United States from certified establishments in the PRC will be subject to ante-mortem and post-mortem inspection (see 9 CFR part 381, subparts J and K), and will be subject to reinspection at United States ports of entry for any conditions which may render the product adulterated or misbranded.

Comment: Individuals and consumer interest groups opposed to the rule questioned whether FSIS can ensure that poultry slaughtered in the PRC will be safe for consumption in the United States. Many individual commenters, three consumer interest groups, and a foodborne illness research center argued that the PRC cannot ensure that their poultry products are safe, because the PRC has produced and exported unsafe products in the past. These commenters were concerned that establishments in the PRC would use antibiotics and chemicals that are banned in the United States; poultry products would contain antibiotic resistant pathogens and harmful residues; similar standards of sanitation would not be maintained; or the products would not be properly labeled. Two consumer interest groups and a few individuals stated that on-site audits would not ensure that exporting establishments meet U.S. requirements. A consumer interest group questioned how the PRC will ensure that each province consistently enforces food safety requirements since the PRC is such a large country. Another such group was concerned that the PRC would certify establishments that do not meet U.S. requirements. One individual expressed concern that residues of a certain type of antibiotic would remain in products.

Response: FSIS has determined that this rule will not adversely affect human health. FSIS explained in a 2006 proposed rule, and again in 2013, its determination that the poultry processing system in the PRC is equivalent to the United States' system. Under FSIS's regulations, initial eligibility to export poultry products to the United States depends on the results of FSIS's documentary reviews and on-site audits of a foreign poultry inspection system. Once the country becomes eligible to ship product to the United States, it is required to continue to submit such documents and other information related to the foreign inspection system as FSIS may find necessary to determine a foreign country's eligibility (9 CFR 381.196(a)(2)(iii)).

During these reviews and audits, FSIS verifies that foreign inspection systems: Have in place a chemical residue control program that is organized by the national government; include random sampling of chemical residues, including veterinary drugs, identified by the exporting country or by FSIS as potential contaminants; and employ methods to deter recurrence of chemical residue violations. FSIS reviewed the PRC's chemical residue program and found that it met FSIS's equivalence criteria. In addition, once the country begins shipping product, the product is subject to reinspection, which includes periodic testing for residues.

Under the regulations, only those establishments that an official of the PRC's poultry inspection system certifies as fully complying with requirements equivalent to the provisions of the PPIA and the regulations issued thereunder will be eligible to export to the United States. As with other countries that FSIS has found equivalent, the PRC may certify any poultry establishment within its territory. The PRC will be required to renew these certifications annually (9 CFR 381.196(a)(3)). The PRC is required to ensure that certified establishments separate, by time or space, product destined for export to the United States from product intended for distribution domestically. All establishments certified by the PRC are subject to review by FSIS, which may terminate the eligibility of an establishment, if it does not comply with FSIS equivalence regulations or if current information about the establishment cannot be obtained (9 CFR 381.196(a)(3)). All certified establishments and records relevant to their certification and operation will be available for on-site and documentary audits by U.S. officials.

The regulations also require that a foreign inspection system, such as that of the PRC, maintain a program to ensure that the requirements equivalent to those in the United States are met. Specifically, the regulations require that a representative of the foreign inspection system periodically visit each establishment certified as complying with requirements equivalent to those of the PPIA and implementing regulations. The regulations also require that this representative prepare written reports documenting findings concerning compliance with requirements equivalent to those of the poultry inspection system in the United States (9 CFR 381.196(a)(2)(iv)). FSIS will evaluate these reports during audits.

Furthermore, each consignment of poultry products exported to the United States from a foreign country must be accompanied by a foreign inspection certificate that certifies that the products: Are sound, healthful, wholesome, clean and otherwise fit for

human food; are not adulterated and have not been treated with and do not contain any dye, chemical, preservative, or ingredient not permitted by FSIS's regulations; have been handled only in a sanitary manner in the foreign country; and are otherwise in compliance with requirements at least equal to those in the PPIA and FSIS's regulations (9 CFR 381.197). Thus, a representative of the Chinese government must certify that the product is not adulterated, does not contain harmful ingredients, and has undergone adequate cooking and processing, as necessary.

In addition to evaluating the PRC's eligibility and performing ongoing audits to ensure that products shipped to the United States are safe, wholesome, and properly labeled and packaged, every shipment of poultry products exported to the United States from the PRC will be subject to reinspection at points of entry for transportation damage, labeling, proper certification, general condition, and accurate count. Other types of inspection will be conducted regularly, including testing for pathogens, residues, and species.

Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and must be re-exported, destroyed, or converted to animal food. Imported poultry products are to be treated as domestic product upon entry into the United States.

Comment: Many individual commenters stated that they preferred to purchase only domestically produced poultry products. Other individuals and two consumer interest groups expressed concern that poultry products from the PRC would not be subject to labeling requirements indicating the country of origin.

Response: All poultry product imports are required to bear on the container in which they are shipped and their immediate container the name of their country of origin, as well as the number assigned by the foreign meat inspection system to the establishment in which they were prepared (9 CFR 381.205–.206). When an imported product is further prepared or processed, the labeling requirements for the resultant product are the same as for domestic product. The addition of a country-of-origin labeling statement is not required by FSIS on further-processed product, although the Agency would approve product labels with the original country-of-origin statement if they are truthful and not misleading and meet all of FSIS's labeling requirements.

Comment: Several individuals expressed a general concern about on-farm practices in China regarding animal raising and feed. Other individuals believed that poultry from the PRC would not be treated humanely.

Response: FSIS is not authorized to mandate production practices on farms, either domestically or as a condition of permitting imports from foreign countries. FSIS regulates the safety of poultry products through its regulatory requirements that apply to slaughter and processing facilities, as well as products in commerce. These include HACCP, sanitation controls, ante- and post-mortem inspection by government inspectors, residue sampling, and *Salmonella* and *Campylobacter* performance standards, all of which are included in the evaluation process for foreign country equivalence.

Poultry are not subject to the Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901, *et seq.*), which requires that humane methods be used for handling and slaughtering livestock. FSIS requires, however, that poultry be handled in a manner that is consistent with good commercial practices, which means they should be treated humanely (see 70 FR 56624, September 28, 2005, *Treatment of Live Poultry Before Slaughter*). FSIS verified that the PRC implements good commercial practices equivalent to those required in domestic establishments.

Comment: A few individuals and a consumer interest group opposed to the rule questioned the timing of the publication of the proposed rule. These commenters argued that FSIS only determined that the PRC was equivalent to re-open U.S. trade of beef products with the PRC. A consumer interest group questioned whether a particular foreign establishment would be certified because it sponsored trips for foreign officials. Several commenters who supported the rule argued that FSIS conducted a rigorous and lengthy assessment of the PRC's poultry inspection system. These commenters also argued that the proposed rule was consistent with U.S. international trade obligations.

Response: FSIS made its equivalence determination based on sound science, and in accordance with international obligations of the United States. The PPIA and the World Trade Organization's Sanitary and Phytosanitary Measures Agreement provide that countries with equivalent inspection systems may export poultry products to the United States. As FSIS explained in the proposed rule, the Agency reviewed the PRC's laws, regulations, and poultry slaughter inspection system as implemented before determining that the PRC's poultry slaughter inspection system is equivalent to the United States' system.

Comment: Many individuals and a consumer interest group expressed support for U.S. domestic poultry production, with an emphasis on local, free-range, poultry. A few commenters were concerned that the PRC would export a large amount of poultry products, resulting in negative effects on domestic poultry producers. One individual asked which domestic industry segments were unlikely to be competitive due to lower labor costs in the PRC. However, comments from the poultry industry argued that the proposed rule would not have a significant impact on their business because the United States is the largest and most efficient poultry producer in the world and has a comparative advantage due to access to cheap, high-quality feed and birds. According to these comments, the United States is also a technological leader in poultry genetics and breeding, feed-compounding, and animal health practices.

Response: As explained in more detail in the economic impact analysis below, FSIS believes the domestic poultry industry will be competitive with poultry from the PRC. Recently, labor costs in the PRC have been rising, which together with high feed costs have pushed the wholesale price of chicken in the PRC to be higher than in the United States. FSIS also does not believe that this rule will adversely affect the U.S. poultry industry, because the volume of trade that results from this rule will likely be small and have little effect on supply and prices.

Comment: One consumer interest group questioned whether FSIS was interacting with the correct PRC government agency. Another such group asserted that FSIS should not find the PRC equivalent because it operated parallel systems for domestic poultry products and products intended for export.

Response: FSIS's equivalence regulations require that before permitting poultry product imports from a foreign country, it find that the country's poultry inspection system complies with requirements equivalent to the PPIA and its implementing regulations, with respect to establishments preparing products for export to the United States (9 CFR 381.196(a)). While FSIS was evaluating the PRC's food safety system for poultry exports, that system was administered

by AQSIQ, the PRC's CCA at that time, in charge of food inspection and implementing a poultry inspection system equivalent to that of the United States. As noted above, the PRC's General Administration of Customs has taken over the functions of the prior CCA, but the reorganization did not result in substantive changes to the PRC's inspection system. The China Food and Drug Administration is responsible for food safety for domestically produced poultry products. As described above, FSIS has conducted a rigorous, comprehensive review of the Chinese food safety system and will continue to verify that the PRC maintains an equivalent inspection system through document review, systems audits, and reinspection of each shipment of poultry from the PRC.

Comment: Two consumer interest groups stated that an establishment in the PRC audited by FSIS was reported in the media as running at higher line speeds than those permitted under FSIS's poultry inspection system. One of these groups asserted that FSIS had only audited the way in which the PRC planned to run its inspection system, instead of observing the system in operation.

Response: As stated in the 2015 audit report, FSIS observed the audited establishments in operation, including the establishment referred to by these commenters. The audit included verification of adequate line speeds, as documented in FSIS's audit report. The PRC's system, as documented and observed, includes line speeds that comply with FSIS's requirements. After the final rule publishes, if the establishment mentioned in these comments is certified by the PRC, it must operate at line speeds in conformance with the inspection system FSIS reviewed and determined equivalent when producing product intended for export to the United States.

Comment: A consumer interest group questioned why a document on FSIS's website was not fully translated.

Response: The document the commenter referred was posted as supporting document to the proposed rule and is available here: *https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/proposed-rules.* It relates to the PRC's compliance with FSIS's final rule, *Modernization of Poultry Slaughter Inspection* (79 FR 49565, August 21, 2014). It is completely translated by AQSIQ, except for a short introductory letter, which does not affect the content.

Comment: Commenters also raised concerns regarding Chinese labor practices and working conditions, the use of a certain pesticide in the United States, greenhouse gasses produced by agricultural activities, and FSIS's previous determination that the PRC is eligible to export processed poultry to the United States if the products are derived from poultry slaughtered in the United States or in other countries eligible to slaughter and export poultry to the United States.

Response: These comments are either beyond the scope of this rulemaking or outside FSIS's authority. This rule is based on FSIS's determination that the PRC's poultry slaughter system is able to provide a level of protection equivalent to the United States' inspection system.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Expected Costs of the Final Rule

The costs of the final rule will accrue primarily to domestic poultry producers in the form of greater competition from the PRC. In the short run, the volume of trade stimulated by this final rule is likely to be small because the PRC only intends to certify five slaughter establishments to provide poultry to certified processing establishments to export fully-cooked poultry products to the United States. Data from the PRC show that these five slaughter establishments will supply poultry to five processing establishments that the PRC will certify as eligible to ship product to the U.S. (three of them intend to export cooked chicken quarter-legs and chicken breasts, one to export cooked duck legs and duck breasts, and one to export roasted boneless duck to the United States).[4] According to the data, the projected volume of exports to the United States will be about 324 million pounds per year for the next five years.[5] Given that the United States domestic annual production volume of ready-to-eat, fully-cooked poultry is about 12,325 million pounds,[6] the projected cooked poultry products from the PRC would only be about 2.6 percent of total United States production in the next five years.[7] The immediate impact on U.S. consumers and domestic processors is likely to be minor, as the low volume of trade is likely to have little effect on supply and prices.

In the long run, domestic producers will probably start to feel competitive pressure of competition if more PRC establishments become certified to export to the United States. However, FSIS believes the domestic poultry industry will be competitive with poultry from the PRC. Recently, labor costs in the PRC have been rising,[8] and the rising labor costs together with high feed costs have pushed the wholesale price of chicken in the PRC to be higher than the United States.[9] Comments from three poultry trade associations on the proposed rule also asserted that the United States is the largest and most efficient poultry producer in the world. According to the poultry trade associations, the United States has a comparative advantage in poultry production and marketing.

Expected Benefits of the Final Rule

The PRC is the second largest poultry producing country in the world, trailing closely behind the United States.[10] If the

[4] Data is from the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, November 2015. The projected annual production of these chicken and duck products at these five processing establishments will be about 838 million pounds per year, which could be sold in the PRC or to other foreign countries.

[5] Data is from the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, November 2015.

[6] Calculated from PHIS data in November 2015. This number cannot be divided by species. If we adjusted it by the proportions of chicken and ducks in total domestic slaughtered poultry, which is 88.3 percent, the volume would be about 10,833 million pounds per year.

[7] If we use 10,833 million pounds (see previous footnote) as the denominator, the projected PRC export would be about 3 percent of United States domestic production of fully-cooked chicken and duck.

[8] Gale, F. and C. Arnade. (2015). Effects of Rising Feed and Labor Costs on China's Chicken Price. *International Food and Agribusiness Management Review, Vol 18, Special Issue A.* 137–150.

[9] Ibid. In addition, the unit price of exported poultry meat and products from China is much higher than that from the U.S. in 2016 and 2017, according to Global Trade Atlas data. We downloaded the data from *https://www.gtis.com,* and it will be available upon request.

[10] See Food Outlook, Food and Agricultural Organization (FAO) of the United Nations, October 2015, p. 49, at *http://www.fao.org/3/a-i5003e.pdf,* accessed 1/11/2016. Also see the same publication

Continued

PRC begins to export other poultry products (for example, if APHIS allows the PRC to export raw chicken products)[11] to the United States and more PRC establishments become certified to be eligible, consumers will likely benefit from more choices and more competitive prices in the marketplace; producers will likely benefit from efficiency gains as they have to become more efficient to be competitive.[12] The Agency did not quantify the value of these benefits because of the lack of predictability associated with the many factors that heavily influence trade patterns and volume. These factors include results of Sanitary and Phytosanitary Standards issues (*e.g.* the avian influenza), exchange rates,[13] and domestic political and economic conditions.

This rule will likely increase trade between the United States and the PRC in poultry products. In the short run, however, the impact is likely to be small as the expected volume of trade stimulated by this rule is likely to be small (see Expected Costs section above).

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this final rule will not have a significant impact on a substantial number of small entities in the United States. The expected trade volume will be small, with little or no effect on all U.S. establishments, regardless of size.

Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this final rule facilitates regulatory cooperation with foreign governments. Therefore, this rule is an E.O. 13771 deregulatory action.

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export poultry and poultry products to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. This information collection was approved under OMB number 0583–0153. The rule contains no other paperwork requirements.

E-Government Act

FSIS and USDA are committed to achieving the purpose of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizens access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this rule and will announce it online through the FSIS web page located at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules.*

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to it through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690–7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

List of Subjects in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is amending 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

§ 381.196 [Amended]

■ 2. In § 381.196, amend paragraph (b) by removing the footnote 2 designation following ''People's Republic of China.''

Done at Washington, DC.

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019–24234 Filed 11–7–19; 8:45 am]

BILLING CODE 3410–DM–P

of June 2017, p.122, at *http://www.fao.org/3/a-i7343e.pdf,* accessed 1/8/2018.

[11] As mentioned above, APHIS has classified the PRC as a region affected by certain animal diseases, so the PRC will only be allowed to export cooked poultry products to the United States.

[12] It is well-established that international trade benefits trade partners because it allows countries to specialize in producing products at which they have a comparative advantage.

[13] The exchange rate affects the relative prices of exports and imports.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0260; Product Identifier 2017–NE–13–AD; Amendment 39–19772; AD 2019–21–06]

RIN 2120–AA64

Airworthiness Directives; Ipeco Pilot and Co-Pilot Seats

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–22–02 for certain Ipeco Holdings Limited (Ipeco) pilot and co-pilot seats. AD 2017–22–02 required modification and re-identification of the affected seats. This AD continues to require modification and re-identification of the affected seats. This AD also requires initial and repetitive inspections of the affected tracklock springs and, depending on the findings, replacement of the tracklock springs with a part eligible for installation. This AD was prompted by reports that the tracklock spring modification required by AD 2017–22–02 does not adequately address the issue of unexpected seat movement during takeoff and landing and the need to add additional seat part numbers (P/Ns) to the applicability. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 13, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 13, 2019.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of December 12, 2017 (82 FR 51552, November 7, 2017).

ADDRESSES: For service information identified in this final rule, contact Ipeco Holdings Limited, Aviation Way, Southend-on-Sea, SS2 6UN, United Kingdom; phone: 44 1702 549371; fax: 44 1702 540782; email: *sales@Ipeco.com*. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0260.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0260; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), regulatory evaluation, any comments received, and other information. The address for Docket Operations is Document Operations, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Neil Doh, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7757; fax: 781–238–7199; email: *neil.doh@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–22–02, Amendment 39–19082 (82 FR 51552, November 7, 2017), (''AD 2017–22–02''). AD 2017–22–02 applied to certain Ipeco pilot and co-pilot seats. The NPRM published in the **Federal Register** on July 19, 2019 (84 FR 34816). The NPRM was prompted by reports of tracklock spring failures occurring on affected seats, including those seats already modified by AD 2017–22–02. The NPRM proposed to retain all the requirements of AD 2017–22–02 and add additional seat P/Ns to the applicability. The NPRM also proposed to require initial and repetitive inspections of the affected tracklock springs and, depending on the findings, replacement of the tracklock springs with a part eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2018–0262, dated December 6, 2018, (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> Occurrences have been reported of pilot/co-pilot unexpected rearward movement during take-off and landing. Investigations determined that horizontal guide block wear, presence of burrs on horizontal centre track and horizontal track lock system weakness (spring tension too low) were causes which contributed to the seat not being correctly locked.
>
> This condition, if not corrected, could lead to further cases of unwanted flight crew seat movement, possibly resulting in reduced control of the aeroplane.
>
> To address this potential unsafe condition, IPECO improved the quality control on the final assembly line and issued the applicable modification SB, providing modification instructions, and EASA issued AD 2016–0256, requiring modification of pre-mod seats and subsequent re-identification with a new P/N.
>
> Since that AD was issued, occurrences of track lock spring failures have been reported on affected seats (including seats already modified as required by EASA AD 2016–0256). Consequently, IPECO published the inspection SB, providing applicable instructions to inspect and replace, if necessary, any affected spring of each affected seat.
>
> For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2016–0256, which is superseded, and requires repetitive inspection of seats and, depending on findings, replacement of affected springs and reporting to IPECO.

You may obtain further information by examining the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0260.

Comments

The FAA gave the public the opportunity to participate in developing this AD. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. The FAA has determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Ipeco Service Bulletin (SB) Number 063–25–08, Revision 00; SB Number 063–25–09, Revision 00; and SB Number 063–25–10, Revision 00; all dated May 31, 2016. The SBs provide instructions, differentiated by the part numbers of the affected pilot and co-pilot seats, for the modification and re-identification of these seats. The FAA also reviewed Ipeco SB Number 063–25–14, Revision 00, dated August 14, 2018. This SB provides instructions for inspection and replacement, if necessary, of affected

tracklock springs. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 110 pilot and co-pilot seats installed on, but not limited to, ATR–GIE Avions de Transport Regional (ATR) 42 and ATR 72 airplanes of U.S. registry. The FAA estimates that seats installed on 34 ATR 42 airplanes and seats installed on 21 ATR 72 airplanes will require modification and inspection. The FAA revised the estimated number of affected seats in this cost estimate to include two affected seats per airplane.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect ATR 42 flight crew seats	0.1 work-hours × $85 per hour = $8.50	$0	$8.50	$289
Modify ATR 42 flight crew seats	2 work-hours × $85 per hour = $170	56	226	7,684
Report results of ATR 42 inspection	1.0 work-hours × $85 per hour = $85	1	86	2,924
Inspect ATR 72 flight crew seats	0.1 work-hours × $85 per hour = $8.50	0	8.50	179
Modify ATR 72 flight crew seats	2 work-hours × $85 per hour = $170	56	226	4,746
Report results of ATR 72 inspection	1.0 work-hours × $85 per hour = $85	1	86	1,806

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the inspection. The FAA has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Remove seat and replace ATR 42 tracklock spring	1.4 work-hours × $85 per hour = $119	$28	$147
Remove seat and replace ATR 72 tracklock spring	1.4 work-hours × $85 per hour = $119	28	147

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all costs in our cost estimate.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2017–22–02, Amendment 39–19082 (82 FR 51552, November 7, 2017), and adding the following new AD:

2019–21–06 Ipeco Holdings Limited: Amendment 39–19772; Docket No. FAA–2019–0260; Product Identifier 2017–NE–13–AD.

(a) Effective Date

This AD is effective December 13, 2019.

(b) Affected ADs

This AD replaces AD 2017–22–02, Amendment 39–19082 (82 FR 51552, November 7, 2017).

(c) Applicability

(1) This AD applies to:

(i) Ipeco Holdings Limited (Ipeco) pilot and co-pilot seats with a part number (P/N) listed in Paragraph 1.A., Planning Information, Tables 1 and 2, of Ipeco Service Bulletin (SB) Number 063–25–14, Revision 00, dated August 14, 2018, and

(ii) Ipeco pilot seat P/N 3A063–0099–01–1 and Ipeco co-pilot seat P/N 3A063–0100–01–1.

(2) These seats are installed on, but not limited to, ATR–GIE Avions de Transport Regional ATR 42 and ATR 72 airplanes.

(d) Subject

Joint Aircraft System Component (JASC) Code 2510, Flight Compartment Equipment.

(e) Unsafe Condition

This AD was prompted by reports of tracklock spring failures occurring on affected seats, including those seats already modified by AD 2017–22–02. The FAA is issuing this AD to prevent unexpected movement of pilot and co-pilot seats on takeoff and landing. The unsafe condition, if not addressed, could result in reduced control of the airplane.

(f) Compliance

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

(g) Required Action

(1) For seats that have not installed the tracklock spring modification kit, within two years after December 12, 2017 (the effective date of AD 2017–22–02), modify and re-identify each affected pilot and co-pilot seat. Use the Accomplishment Instructions of Ipeco SB Number 063–25–08, Revision 00; Ipeco SB Number 063–25–09, Revision 00; or Ipeco SB Number 063–25–10, Revision 00; all dated May 31, 2016, as appropriate, to do the modification and re-identification.

(2) For all affected seats:

(i) Within 750 flight hours (FHs) after the effective date of this AD, and, thereafter at intervals not to exceed 750 FHs, inspect the tracklock spring of each seat in accordance with the Accomplishment Instructions, paragraph 3.2, of the Ipeco SB Number 063–25–14, Revision 00, dated August 14, 2018.

(ii) If, during any inspection as required by paragraph (g)(2)(i) of this AD, any damage on, or incorrect installation of, any tracklock spring is found on the pilot or co-pilot seat, before further flight, replace both tracklock springs of the affected seat with a part eligible for installation using the Accomplishment Instructions, paragraphs 3.3.3.1 or 3.3.3.2, as applicable, of the Ipeco SB Number 063–25–14, Revision 00, dated August 14, 2018.

(3) Within 30 days after the initial and repetitive inspections, and thereafter for two years after the effective date of this AD, send the inspection results, including no findings, to Ipeco at *technicalsupport@ipeco.com.*

(h) Installation Prohibition

After the effective date of this AD, do not install any pilot or co-pilot seat identified in paragraph (c)(1)(i) of this AD unless the seat is modified and re-identified as specified in paragraph (g)(1) of this AD.

(i) Definitions

(1) For the purpose of this AD, ''damage'' includes cracks, breaks, corrosion, or deformation of the tracklock spring.

(2) For the purpose of this AD, ''incorrect installation'' is installing the tracklock spring at an angle or position different from the angle or postion shown in Figures 6 and 7 of Ipeco SB Number 063–25–14, Revision 00, dated August 14, 2018.

(3) For the purpose of this AD, a ''part eligible for installation'' is:

(i) A modified seat provided, before installation, it has passed an inspection (no damage or defect found); and

(ii) a tracklock spring provided that it passed an inspection (no damage or defect found).

(j) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(l) Related Information

(1) For more information about this AD, contact Neil Doh, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7757; fax: 781–238–7199; email: *neil.doh@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2018–0262, dated December 6, 2018, for more information. You may examine the EASA AD in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2019–0260.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on December 13, 2019.

(i) Ipeco Service Bulletin (SB) Number 063–25–14, Revision 00, dated August 14, 2018.

(ii) Reserved.

(4) The following service information was approved for IBR on December 12, 2017 (82 FR 51552, November 7, 2017).

(i) Ipeco SB Number 063–25–08, Revision 00, dated May 31, 2016.

(ii) Ipeco SB Number 063–25–09, Revision 00, dated May 31, 2016.

(iii) Ipeco SB Number 063–25–10, Revision 00, dated May 31, 2016.

(5) For Ipeco service information identified in this AD, contact Ipeco Holdings Limited, Aviation Way, Southend-on-Sea, SS2 6UN,

United Kingdom; phone: 44 1702 549371; fax: 44 1702 540782; email: *sales@Ipeco.com*.

(6) You may view this service information at FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

(7) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Burlington, Massachusetts, on October 25, 2019.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019–24378 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0690; Product Identifier 2018–CE–022–AD; Amendment 39–19761; AD 2019–20–08]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace Corporation (Gulfstream) Model G–IV and Model GIV–X airplanes. This AD was prompted by a revision to the airworthiness limitations section (ALS) of the aircraft maintenance manual (AMM) based on fatigue and damage tolerance testing and updated analysis. This AD requires revising the maintenance or inspection program to incorporate updated inspection requirements and life limits that address fatigue cracking of principal structural elements. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 13, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 13, 2019.

ADDRESSES: For service information identified in this final rule, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone: (800) 810–4853; fax: (912) 965–3520; email: *pubs@gulfstream.com;* internet: *https://www.gulfstream.com/en/contact/support/#form*. You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0690.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0690; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Ronald ''Ron'' Wissing, Airframe Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5552; fax: (404) 474–5606; email: *ronald.wissing@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Gulfstream Model G–IV and Model GIV–X airplanes. The SNPRM published in the **Federal Register** on April 2, 2019 (84 FR 12530). The FAA preceded the SNPRM with a notice of proposed rulemaking (NPRM) that published in the **Federal Register** on August 2, 2018 (83 FR 37771). The NPRM proposed to require revising the ALS in the AMM to incorporate new inspections and life limits contained in Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision B, dated March 12, 2018. The NPRM was prompted by a revision to the ALS of the AMM based on fatigue and damage tolerance testing and updated analysis.

After the FAA issued the NPRM, Gulfstream updated the life limits in the ALS and issued Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision D, dated August 20, 2018. Revision D differs from Revision B in that the part number (P/N) for the rudder for Model GIV airplanes has been corrected to reflect P/N 1159CS30004, and new life limits for fuselage cockpit side post P/N 1159BM50025–5 and P/N 1159BM50025–6 have been added per Revision C. The SNPRM proposed to require the later revision of the service information. The FAA is issuing this AD to address the unsafe condition on these products.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the SNPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision D, dated August 20, 2018. This document contains new and revised inspections and life limits pertaining to fatigue cracking of principal structural elements. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 711 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise ALS and AMM	20 work-hours × $85 per hour = $1,700.	Not applicable	$1,700	$1,208,700

The extent of damage found during the inspection may vary from airplane to airplane. The FAA has no way of determining the number of airplanes that might need repairs or the cost of such repairs for each airplane.

Authority for This Rulemaking

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

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–20–08 Gulfstream Aerospace Corporation: Amendment 39–19761; Docket No. FAA–2018–0690; Product Identifier 2018–CE–022–AD.

(a) Effective Date

This AD is effective December 13, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model G–IV airplanes, certificated in any category, serial numbers 1000 through 1535; and Model GIV–X airplanes, certificated in any category, serial numbers 4001 through 4363.

Note 1 to paragraph (c) of this AD: Model G–IV airplanes are also referred to by the marketing designations G300 and G400. Model GIV–X airplanes are also referred to by the marketing designations G350 and G450.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 27, Flight Controls; 32, Landing Gear; 52, Doors; 53, Fuselage; 55, Stabilizers; 57, Wings; 71, Power Plant-General; and 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by a revision to the airworthiness limitations section (ALS) of the Model G–IV and Model GIV–X aircraft maintenance manuals based on fatigue and damage tolerance testing and updated analysis. The FAA is issuing this AD to detect and correct fatigue cracking of principal structural elements (PSEs). This unsafe condition, if unaddressed, could result in reduced structural integrity of a PSE or critical component and lead to loss of control of the airplane.

(f) Compliance

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

(g) Airplane Maintenance Manual Revisions

Within 12 months after December 13, 2019 (the effective date of this AD), revise the ALS of your maintenance or inspection program (*e.g.,* maintenance manual) to incorporate the airworthiness limitations specified in Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision D, dated August 20, 2018, as applicable to your model and serial number airplane.

(h) No Alternative Actions or Intervals

After the maintenance or inspection program (*e.g.,* maintenance manual) has been revised as required by paragraph (g) of this AD, no alternative inspections or intervals may be used unless approved as an alternative method of compliance in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(j) Related Information

For more information about this AD, contact Ronald ''Ron'' Wissing, Airframe Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia

30337; phone: (404) 474–5552; fax: (404) 474–5606; email: *ronald.wissing@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision D, dated August 20, 2018.

(ii) [Reserved]

(3) For Gulfstream Aerospace Corporation service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone: (800) 810–4853; fax: (912) 965–3520; email: *pubs@gulfstream.com;* internet: *https://www.gulfstream.com/en/contact/support/#form.*

(4) You may view this service information at FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on October 29, 2019.

Pat Mullen,

Aircraft Certification Service Manager, Small Airplane Standards Branch, AIR–690.

[FR Doc. 2019–24324 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31282; Amdt. No. 549]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: *Effective:* 0901 UTC, December 5, 2019.

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 73125. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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 95

Airspace, Navigation (air).

Issued in Washington, DC on November 1, 2019.

Rick Domingo,

Executive Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, December 5, 2019.

■ 1. The authority citation for part 95 continues to read as follows:

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

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 549 Effective Date, December 05, 2019]

From	To	MEA	MAA
§ 95.4000 High Altitude RNAV Routes **§ 95.4121 RNAV Route Q121 Is Amended To Read In Part**			
POCATELLO, ID VOR/DME	SWTHN, MT WP	*24000	45000
*18000—GNSS MEA			

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT—Continued
[Amendment 549 Effective Date, December 05, 2019]

From	To	MEA	MAA
*DME/DME/IRU MEA			
§ 95.4156 RNAV Route Q156 Is Amended To Read In Part			
HEXOL, MT FIX	SWTHN, MT WP	*24000	45000
*18000—GNSS MEA *DME/DME/IRU MEA SWTHN, MT WP	JELRO, SD FIX	*28000	45000
*18000—GNSS MEA *DME/DME/IRU MEA JELRO, SD FIX	KEKPE, SD WP	*28000	45000
*18000—GNSS MEA *DME/DME/IRU MEA KEKPE, SD WP	UFFDA, MN WP	*28000	45000
*18000—GNSS MEA *DME/DME/IRU MEA UFFDA, MN WP	HSTIN, MN WP	*28000	45000
*18000—GNSS MEA *DME/DME/IRU MEA			

From	To	MEA
§ 95.6001 Victor Routes—U.S **§ 95.6004 VOR Federal Airway V4 Is Amended To Read In Part**		
CHARLESTON, WV VOR/DME	REACH, WV FIX	4000
§ 95.6020 VOR Federal Airway V20 Is Amended To Read In Part		
CORPUS CHRISTI, TX VORTAC	BETZY, TX FIX	1800
§ 95.6035 VOR Federal Airway V35 Is Amended To Read In Part		
GLADE SPRING, VA VOR/DME	MACET, WV FIX	#6500
#GZG TO COP UNUSABLE EXCEPT FOR AIRCRAFT WITH SUITABLE RNAV SYSTEM WITH GPS		
MACET, WV FIX	CHARLESTON, WV VOR/DME	
	N BND	4500
	S BND	6500
§ 95.6070 VOR Federal Airway V70 Is Amended To Read In Part		
CORPUS CHRISTI, TX VORTAC	BETZY, TX FIX	1800
§ 95.6115 VOR Federal Airway V115 Is Amended To Read In Part		
HAZARD, KY VOR/DME	*CHARLESTON, WV VOR/DME	**6000
*4800—MCA	CHARLESTON, WV VOR/DME, SW BND.	
**4000—GNSS MEA		
§ 95.6133 VOR FEDERAL AIRWAY V133 Is Amended To Read In Part		
STOVE, VA FIX	PINEE, WV FIX	*13000
*7000—MOCA		
PINEE, WV FIX	*CHARLESTON, WV VOR/DME	
	N BND	**7000
	S BND	**13000
*8500—MCA	CHARLESTON, WV VOR/DME, S BND	.....
**5600—MOCA		
**5600—GNSS MEA		
§ 95.6155 VOR Federal Airway V155 Is Amended To Read In Part		
WIPER, NC FIX	LAWRENCEVILLE, VA VORTAC	#*8000
*2000—MOCA		
*2300—GNSS MEA		
#LAWRENCEVILLE R–225 UNUSABLE, USE RALEIGH/ DURHAM R–046		
*MANGE, VA FIX	FLAT ROCK, VA VORTAC	**5000
*5000—MRA		
**1800—MOCA		
**2000—GNSS MEA		

From	To	MEA
§ 95.6257 VOR Federal Airway V257 Is Amended To Read In Part		
PHOENIX, AZ VORTAC	AVENT, AZ FIX	
	NW BND	14000
	SE BND	5000
*8000—MRA		
*9400—MCA	PHOENIX, AZ VORTAC, NW BND.	
*AVENT, AZ FIX	**BANYO, AZ FIX	
	NW BND	14000
	SE BND	5000
*8000—MRA		
**6000—MRA		
*BANYO, AZ FIX	COYOT, AZ FIX	
	NW BND	**14000
	SE BND	**9000
*6000—MRA		
**8100—MOCA		
COYOT, AZ FIX	*MAIER, AZ FIX	**14000
*14000—MCA	MAIER, AZ FIX, SE BND.	
**9000—GNSS MEA		
MAIER, AZ FIX	*DRAKE, AZ VORTAC	
	NW BND	10000
	SE BND	14000
*12000—MCA	DRAKE, AZ VORTAC, SE BND.	
§ 95.6258 VOR Federal Airway V258 Is Amended To Read In Part		
CHARLESTON, WV VOR/DME	BECKLEY, WV VOR/DME	5500
§ 95.6309 VOR FEDERAL AIRWAY V309 Is Amended To Read In Part		
CHARLESTON, WV VOR/DME	JULEA, WV FIX	**5000
*5000—MRA		
*5700—MCA	JULEA, WV FIX, NE BND	
**3200—MOCA		
**3200—GNSS MEA		
*JULEA, WV FIX	RANDE, WV FIX	**7000
*5000—MRA		
**3200—MOCA		
**3200—GNSS MEA		
§ 95.6378 VOR Federal Airway V378 Is Amended To Read In Part		
BALTIMORE, MD VORTAC	*BELAY, MD FIX	2300
*9500—MCA	BELAY, MD FIX, NE BND.	
§ 95.6454 VOR FEderal Airway V454 Is Amended To Read In Part		
LIBERTY, NC VORTAC	NOKIY, VA FIX	*6000
*3000—GNSS MEA		
NOKIY, VA FIX	LAWRENCEVILLE, VA VORTAC	*8000
*3000—GNSS MEA		
#LAWRENCEVILLE R–242 UNUSABLE, USE LIBERTY R–056		
LAWRENCEVILLE, VA VORTAC	JUNKI, VA FIX	#*6000
*1900—MOCA		
*2000—GNSS MEA		
#LAWRENCEVILLE R–059 UNUSABLE, USE HOPEWELL R–237.		

Airway Segment		Changeover points	
From	To	Distance	From
§ 95.8003 VOR Federal Airway Changeover Point V258 Is Amended To Modify Changeover Point			
CHARLESTON, WV VOR/DME	BECKLEY, WV VOR/DME	20	CHARLESTON

[FR Doc. 2019–24345 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–504]

Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV

Correction

In rule document 2019–12723 beginning on page 27943 in the issue of Monday, June 17, 2019, make the following correction:

§ 1308.14 [Corrected]

On page 27947, in the third column, in § 1308.14(f)(12), in the second line ''car-bamate'' should read ''carbamate''.

[FR Doc. C1–2019–12723 Filed 11–7–19; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 478

[Docket No. ATF 2019R–03; AG Order No. 4576–2019]

Removal of Expired Regulations Concerning Commerce in Firearms and Ammunition; Correction

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Final rule.

SUMMARY: On April 1, 2019, the Department of Justice published in the **Federal Register** a final rule making technical changes to remove expired, obsolete, or unnecessary regulations; correct specific headings; and reflect changes to nomenclature in the Bureau of Alcohol, Tobacco, Firearms, and Explosives regulations related to the commerce in firearms and ammunition. That document inadvertently included an incomplete revision to remove all words related to an expired regulation. This final rule corrects the April 2019 amendment by revising the section to complete the removal of the expired regulation.

DATES: This rule is effective November 8, 2019.

FOR FURTHER INFORMATION CONTACT: Shermaine Kenner, Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue NE, Washington, DC 20226; telephone: (202) 648–7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) administers regulations published in title 27, Code of Federal Regulations (CFR), part 478, concerning commerce in firearms and ammunition. On April 1, 2019, the Department of Justice (DOJ) published in the **Federal Register** a final rule that made technical amendments in ATF regulations in the CFR (84 FR 12093). The technical changes made in this rule included the removal of expired regulations and regulations that are no longer applicable; the correction of section headings for accuracy; and a change in nomenclature resulting from the transfer of ATF to the Department of Justice from the Department of the Treasury pursuant to the Homeland Security Act of 2002.

Several sections were removed or amended because the statute that formed the basis of those regulations is no longer in effect. The Public Safety and Recreational Firearms Act (the Act), enacted as part of the Violent Crime Control and Law Enforcement Act of 1994, Pub. L. 103–322, Title XI (1994), established a 10-year prohibition on the manufacture, transfer, or possession of ''semiautomatic assault weapons,'' as defined in the Act, as well as large capacity feeding devices. The Act expired on September 13, 2004, and the final rule was issued to remove or amend the regulatory provisions that had, in whole or in part, implemented that Act as they are no longer effective.

The April 2019 technical amendments inadvertently failed to remove all words related to the expired regulation that were included in 27 CFR 478.171. This final rule corrects the changes in the CFR made by the 2019 technical amendments by amending § 478.171 to remove ''and manufactured after September 13, 1994, '' and ''or were'' in the last sentence of the paragraph and to add ''was'' before ''exported'' in the last sentence of the paragraph.

II. Statutory Orders and Executive Review

A. Executive Orders 12866, 13563, and 13771

This rule has been drafted and reviewed in accordance with Executive Orders 12866, '' Regulatory Planning and Review,'' section 1(b), The Principle of Regulation; Executive Order 13563, ''Improving Regulation and Regulatory Review,''section 1(b), General Principles of Regulation; and Executive Order 13771, '' Reducing Regulation and Controlling Regulatory Costs.''

This rule makes technical corrections to eliminate outdated and incorrect terminology and improve the clarity of the regulations, and makes no substantive changes. The Department has determined that this final rule is not a ''significant regulatory action'' as defined in Executive Order 12866, section 3(f). Accordingly, this final rule has not been reviewed by the Office of Management and Budget.

Finally, because this rule is not a significant regulatory action, it is not subject to the requirements of Executive Order 13771. There are no costs associated with this regulation; however, it benefits the industry in that it removes outdated regulations and provides clarity for the regulated industry. Because there are no costs associated with this final rule, there are no monetized benefits. This rule is considered a deregulatory action under Executive Order 13771.

B. Executive Order 13132

This final rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, ''Federalism,'' the Attorney General has determined that this regulation does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

C. Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform.''

D. Administrative Procedure Act

Under the Administrative Procedure Act (''APA''), 5 U.S.C. 553(b)(3)(B), an agency may, for good cause, find the usual requirements of prior notice and comment are impracticable, unnecessary, or contrary to the public interest. Currently, 27 CFR part 478 contains references to expired regulations and has obsolete, outdated, and incorrect terminology that may be confusing to the public. The rule makes technical corrections to improve the clarity and accuracy of the regulations and makes no substantive changes. For

these reasons, the agency has determined that publishing a noticed of proposed rulemaking and providing opportunity for public comment is unnecessary.

Further, the APA permits an agency to make this rule effective upon the date of publication because it is not a substantive rule. *See* 5 U.S.C. 553(d). Furthermore, the Department finds that there is good cause for the final rule to take effect upon publication, since the revisions made by this rule are minor, non-substantive, and technical, and there is no reason to delay these changes. *Id.*

E. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 603, 604, and 605(b), a Regulatory Flexibility Analysis is not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1525.

G. Paperwork Reduction Act of 1995

This final rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act 44 U.S.C. 3501–3521.

H. Congressional Review Act

Pursuant to the Congressonal Review Act, 5 U.S.C. 801 *et seq.,* the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 27 CFR Part 478

Administrative practice and procedure, Arms and munitions, Customs duties and inspection, Exports, Imports, Intergovernmental relations, Law enforcement officers, Military personnel, Penalties, Reporting and recordkeeping requirements, Research, Seizures and forfeitures, Transportation.

Authority and Issuance

Accordingly, for the reasons discussed in the preamble, 27 CFR part 478 is amended as follows:

PART 478—COMMERCE IN FIREARMS AND AMMUNITION

■ 1. The authority citation for 27 CFR part 478 continues to read as follows:

Authority: 5 U.S.C. 552(a); 18 U.S.C. 921–931; 44 U.S.C. 3504(h).

§ 478.171 [Amended]

■ 2. Amend § 478.171 by removing ''and manufactured after September 13, 1994,'' and ''or were'' in the last sentence of the paragraph and adding ''was'' before ''exported'' in the last sentence of the paragraph.

Dated: November 1, 2019.

William P. Barr,

Attorney General.

[FR Doc. 2019–24301 Filed 11–7–19; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2019–0776]

Special Local Regulations; San Diego Parade of Lights, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the San Diego Parade of Lights special local regulations on the waters of San Diego Bay, California on December 8, 2019 and December 15, 2019. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 5 p.m. through 8:30 p.m. on December 8, 2019 and December 15, 2019 for Item 5 in Table 1 of § 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication of enforcement, call or email Lieutenant Briana Biagas, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email *D11MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the San Diego Parade of Lights in San Diego Bay, CA in Table 1, Item 5 of that section from 5 p.m. until 8:30 p.m. on December 8, 2019 and December 15, 2019. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities and area for this event. During the enforcement periods and under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: November 4, 2019.

D.P. Montoro,

Captain, U.S. Coast Guard, Acting Captain of the Port San Diego.

[FR Doc. 2019–24383 Filed 11–7–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0859]

RIN 1625–AA00

Safety Zone; Coast Guard PSU–312 Training Exercise South Bay, San Francisco Bay, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of San Francisco Bay offshore of San Francisco, CA in support of the Coast Guard PSU–312

training exercise. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the Coast Guard PSU–312 on-water training and associated operations. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port San Francisco or a designated representative.

DATES: This rule is effective from 9:00 a.m. on November 15, 2019 until 10:00 p.m. on November 16, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0859 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 LT Emily K. Rowan, Waterways Management, U.S. Coast Guard; telephone (415) 399–7443, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port San Francisco
DHS Department of Homeland Security
§ 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 with respect to this rule because it is impracticable. The Coast Guard received the final details of the training on October 8, 2019. It is impracticable to go through the entire notice and comment rulemaking process because the Coast Guard must establish this temporary safety zone by November 15, 2019 and lacks sufficient time to provide a reasonable comment period and 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 rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to protect personnel, vessels, and the marine environment in the navigable waters around the potentially hazardous on-water training and associated operations involving vessels firing blank rounds.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the Coast Guard PSU–312 training operations scheduled to occur on November 15, 2019 and November 16, 2019 will be a safety concern for anyone within the designated exercise area. The on-water training will involve vessels firing blank rounds. For this reason, this temporary safety zone is needed to protect personnel, vessels, and the marine environment in the navigable waters surrounding the potentially hazardous activity.

IV. Discussion of the Rule

This rule establishes a safety zone around the Coast Guard PSU–312 training operations offshore of Pier 96 in San Francisco Bay, San Francisco, CA on November 15, 2019 from 9:00 a.m. until 10:00 p.m., and on November 16, 2019 from 9:00 a.m. until 10:00 p.m. The safety zone will encompass the navigable waters of San Francisco Bay, from surface to bottom, within the area formed by connecting the following latitude and longitude points in the following order: 37°44.72′ N 122°22.35′ W, thence to 37°44.89′ N 122°22.12′ W, thence to 37°44.48′ N 122°21.73′ W, thence to 37°44.30′ N 122°22.05′ W, thence to 37°44.41′ N 122°22.06′ W (NAD 83), and thence to the point of beginning; or as announced via Broadcast Notice to Mariners.

This regulation is needed to keep persons and vessels away from the immediate vicinity of the training operations to ensure the safety of personnel, vessels, and the marine environment. Except for persons or vessels authorized by the COTP or the COTP's designated representative, no person or vessel may enter or remain in the restricted area. A ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

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 limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the water encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified to ensure the safety zone will result in minimum impact. The vessels desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP's designated representative.

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 (Public Law 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 U.S. Coast Guard Environmental Planning Policy, 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 that will prohibit entry to the area surrounding the potentially hazardous Coast Guard training operations. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of Department of Homeland Security Directive 023–01. 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.T11–006 to read as follows:

§ 165.T11–006 Safety Zone; Coast Guard PSU–312 Training Exercise South Bay, San Francisco Bay, San Francisco, CA.

(a) *Location.* The following is a safety zone: The safety zone will encompass the navigable waters of San Francisco Bay, from surface to bottom, within the area formed by connecting the following latitude and longitude points in the following order: 37°44.72′ N 122°22.35′ W, thence to 37°44.89′ N 122°22.12′ W, thence to 37°44.48′ N 122°21.73′ W, thence to 37°44.30′ N 122°22.05′ W, thence to 37°44.41′ N 122°22.06′ W (NAD 83), and thence to the point of beginning; or as announced via Broadcast Notice to Mariners.

(b) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart B of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced on November 15, 2019 from 9:00 a.m. until 10:00 p.m., and on November 16, 2019 from 9:00 a.m. until 10:00 p.m.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced in accordance with § 165.7.

Dated: November 1, 2019.

Marie B. Byrd,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2019–24380 Filed 11–7–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0530]

RIN 1625–AA00

Safety Zone; Ohio River, Miles 103.0 to 105.0, Moundsville, WV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Ohio River from Mile 103.0 to Mile 105.0. This action is necessary to protect persons, vessels, and the marine environment from potential hazards associated with power line work across the river. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: This rule is effective from November 11, 2019 through December 11, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0530 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 Petty Officer Trevor VanNatta, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Trevor.J.VanNatta@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Marine Safety Unit Pittsburgh
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)(3)(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. This safety zone must be established by November 11, 2019 and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone until after the date of the power line work and compromise public safety.

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 this rule would be contrary to the public interest because immediate action is necessary to respond to the potential safety hazards associated with power line work, which could pose a risk to the operation and waterways users if the normal vessel traffic were to interfere with the work. Possible hazards include risks of injury or death from near or actual contact among working vessels and mariners traversing through the safety zone.

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 Marine Safety Unit Pittsburgh (COTP) has determined that potential hazards associated with power line pulls across the Ohio River will be a safety hazard for anyone within a two mile stretch of the Ohio River. The rule is needed to protect people from power line work which could pose a risk to the operation and waterways users if the normal vessel traffic were to interfere with the work. Possible hazards include risks of injury or death from near or actual contact among working vessels and mariners traversing through the safety zone.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that will be enforced from 7 a.m. through 5:30 p.m. from November 11, 2019 through December 11, 2019. The safety zone will cover all navigable waters of the Ohio River, from mile 103.0 to mile 105.0. The duration of the zone is intended to protect persons, vessels, and the marine environment on these navigable waters before, during, and after the power line pulls. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a 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 Marine Safety Unit Pittsburgh. Persons and vessels seeking entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or by telephone at (412) 221–0807. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful instructions of the COTP or a designated representative. Breaks in the power line work will occur during the enforcement periods, which will allow vessels to pass through the safety zone. The COTP or a designated representative will inform the public of the enforcement period for the safety zone as well as any changes in the schedule through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

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, duration, and location of the safety zone. This rule will impact a two mile stretch of the Ohio River from 7 a.m. through 5:30 p.m. daily from November 11, 2019

through December 11, 2019. Breaks in the power line work will occur during the enforcement periods, which will allow for vessels to pass through the safety zone. Moreover, the Coast Guard will issue Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and BNMs via VHF–FM marine channel 16 about the zones and the rule allows vessels to seek permission from the COTP or a designated representative to enter the zones.

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 temporary safety zone lasting ten and a half hours on each day that will prohibit entry on a two mile stretch of the Ohio River. 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.T08–0530 to read as follows:

§ 165.T08–0530 Safety Zone; Ohio River, miles 103.0 to 105.0, Moundsville, WV.

(a) *Location.* The following area is a temporary safety zone: All navigable waters of the Ohio River from mile 103.0 to mile 105.0.

(b) *Effective period.* This section is effective from November 11, 2019 through December 11, 2019.

(c) *Enforcement period.* This section will be enforced from 7 a.m. through 5:30 p.m. daily. Breaks in the power line work will occur during the enforcement periods, which will allow vessels to pass through the safety zone. The Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative will provide notice of breaks as appropriate under paragraph (e) of this section.

(d) *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 Marine Safety Unit Pittsburgh (COTP) or a 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 Marine Safety Unit Pittsburgh.

(2) Persons and vessels seeking entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or by telephone at (412) 221–0807.

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

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement period for the safety zone as well as any changes in the schedule through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

A.W. Demo,

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

[FR Doc. 2019–24411 Filed 11–7–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2019–0077 and 0078; FRL–10001–92–OLEM]

National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''the EPA'' or ''the agency'') in determining which sites warrant further investigation. These further investigations will allow the EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds two sites to the General Superfund section of the NPL.

DATES: The document is effective on December 9, 2019.

ADDRESSES: Contact information for the EPA Headquarters:

- Docket Coordinator, Headquarters; U.S. Environmental Protection Agency; CERCLA Docket Office; 1301 Constitution Avenue NW; William Jefferson Clinton Building West, Room 3334, Washington, DC 20004, 202/566–0276.

The contact information for the regional dockets is as follows:

- Holly Inglis, Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA, Superfund Records and Information Center, 5 Post Office Square, Suite 100, Boston, MA 02109–3912; 617/918–1413.
- James Desir, Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007–1866; 212/637–4342.
- Lorie Baker (ASRC), Region 3 (DE, DC, MD, PA, VA, WV), U.S. EPA, Library, 1650 Arch Street, Mailcode 3HS12, Philadelphia, PA 19103; 215/814–3355.
- Cathy Amoroso, Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street SW, Mailcode 9T25, Atlanta, GA 30303; 404/562–8637.
- Todd Quesada, Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Librarian/SFD Records Manager SRC–7J, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604; 312/886–4465.
- Brenda Cook, Region 6 (AR, LA, NM, OK, TX), U.S. EPA, 1445 Ross Avenue, Suite 1200, Mailcode 6SFTS, Dallas, TX 75202–2733; 214/665–7436.
- Kumud Pyakuryal, Region 7 (IA, KS, MO, NE), U.S. EPA, 11201 Renner Blvd., Mailcode SUPRSTAR, Lenexa, KS 66219; 913/551–7956.
- Victor Ketellapper, Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 1595 Wynkoop Street, Mailcode 8EPR–B, Denver, CO 80202–1129; 303/312–6578.
- Eugenia Chow, Region 9 (AZ, CA, HI, NV, AS, GU, MP), U.S. EPA, 75 Hawthorne Street, Mailcode SFD 6–1, San Francisco, CA 94105; 415/972–3160.
- Ken Marcy, Region 10 (AK, ID, OR, WA), U.S. EPA, 1200 6th Avenue, Mailcode ECL–112, Seattle, WA 98101; 206/463–1349.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone: (703) 603–8852, email: *jeng.terry@epa.gov*, Site Assessment and Remedy Decisions Branch, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation (Mailcode 5204P), U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue NW, Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. What are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA'' or ''the Act''), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act (''SARA''), Public Law 99–499, 100 Stat. 1613 *et seq.*

B. What is the NCP?

To implement CERCLA, the EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan (''NCP''), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances, or releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. The EPA has revised the NCP on several occasions. The most recent comprehensive revision was on March 8, 1990 (55 FR 8666).

As required under section 105(a)(8)(A) of CERCLA, the NCP also includes ''criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable, taking into account the potential urgency of such action, for the purpose of taking removal action.'' ''Removal'' actions are defined broadly and include a wide range of actions taken to study, clean up, prevent or otherwise address releases and threatened releases of hazardous substances, pollutants or contaminants (42 U.S.C. 9601(23)).

C. What is the National Priorities List (NPL)?

The NPL is a list of national priorities among the known or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The list, which is appendix B of the NCP (40 CFR part 300), was required under section 105(a)(8)(B) of CERCLA, as amended. Section 105(a)(8)(B) defines the NPL as a list of ''releases'' and the highest priority ''facilities'' and requires that the NPL be revised at least annually. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is of only limited significance, however, as it does not assign liability to any party or to the owner of any specific property. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

For purposes of listing, the NPL includes two sections, one of sites that are generally evaluated and cleaned up by the EPA (the ''General Superfund section'') and one of sites that are owned or operated by other federal agencies (the ''Federal Facilities section''). With respect to sites in the Federal Facilities section, these sites are generally being addressed by other federal agencies. Under Executive Order 12580 (52 FR 2923, January 29, 1987) and CERCLA section 120, each federal agency is responsible for carrying out most response actions at facilities under its own jurisdiction, custody or control, although the EPA is responsible for preparing a Hazard Ranking System (''HRS'') score and determining whether the facility is placed on the NPL.

D. How are sites listed on the NPL?

There are three mechanisms for placing sites on the NPL for possible remedial action (see 40 CFR 300.425(c) of the NCP): (1) A site may be included on the NPL if it scores sufficiently high on the HRS, which the EPA promulgated as appendix A of the NCP (40 CFR part 300). The HRS serves as a screening tool to evaluate the relative potential of uncontrolled hazardous substances, pollutants or contaminants to pose a threat to human health or the environment. On December 14, 1990 (55 FR 51532), the EPA promulgated revisions to the HRS partly in response to CERCLA section 105(c), added by SARA. On January 9, 2017 (82 FR 2760), a subsurface intrusion component was added to the HRS to enable the EPA to consider human exposure to hazardous substances or pollutants and contaminants that enter regularly occupied structures through subsurface intrusion when evaluating sites for the NPL. The current HRS evaluates four pathways: Ground water, surface water, soil exposure and subsurface intrusion, and air. As a matter of agency policy, those sites that score 28.50 or greater on the HRS are eligible for the NPL. (2) Each state may designate a single site as its top priority to be listed on the NPL, without any HRS score. This provision of CERCLA requires that, to the extent practicable, the NPL include one facility designated by each state as the greatest danger to public health, welfare or the environment among known facilities in the state. This mechanism for listing is set out in the NCP at 40 CFR 300.425(c)(2). (3) The third mechanism for listing, included in the NCP at 40 CFR 300.425(c)(3), allows certain sites to be listed without any HRS score, if all of the following conditions are met:

- The Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service has issued a health advisory that recommends dissociation of individuals from the release.
- The EPA determines that the release poses a significant threat to public health.
- The EPA anticipates that it will be more cost-effective to use its remedial authority than to use its removal authority to respond to the release.

The EPA promulgated an original NPL of 406 sites on September 8, 1983 (48 FR 40658) and generally has updated it at least annually.

E. What happens to sites on the NPL?

A site may undergo remedial action financed by the Trust Fund established under CERCLA (commonly referred to as the ''Superfund'') only after it is placed on the NPL, as provided in the NCP at 40 CFR 300.425(b)(1). (''Remedial actions'' are those ''consistent with a permanent remedy, taken instead of or in addition to removal actions'' (40 CFR 300.5).) However, under 40 CFR 300.425(b)(2), placing a site on the NPL ''does not imply that monies will be expended.'' The EPA may pursue other appropriate authorities to respond to the releases, including enforcement action under CERCLA and other laws.

F. Does the NPL define the boundaries of sites?

The NPL does not describe releases in precise geographical terms; it would be neither feasible nor consistent with the limited purpose of the NPL (to identify releases that are priorities for further evaluation), for it to do so. Indeed, the precise nature and extent of the site are typically not known at the time of listing.

Although a CERCLA ''facility'' is broadly defined to include any area where a hazardous substance has ''come to be located'' (CERCLA section 101(9)), the listing process itself is not intended to define or reflect the boundaries of such facilities or releases. Of course,

HRS data (if the HRS is used to list a site) upon which the NPL placement was based will, to some extent, describe the release(s) at issue. That is, the NPL site would include all releases evaluated as part of that HRS analysis.

When a site is listed, the approach generally used to describe the relevant release(s) is to delineate a geographical area (usually the area within an installation or plant boundaries) and identify the site by reference to that area. However, the NPL site is not necessarily coextensive with the boundaries of the installation or plant, and the boundaries of the installation or plant are not necessarily the ''boundaries'' of the site. Rather, the site consists of all contaminated areas within the area used to identify the site, as well as any other location where that contamination has come to be located, or from where that contamination came.

In other words, while geographic terms are often used to designate the site (*e.g.,* the ''Jones Co. Plant site'') in terms of the property owned by a particular party, the site, properly understood, is not limited to that property (*e.g.,* it may extend beyond the property due to contaminant migration), and conversely may not occupy the full extent of the property (*e.g.,* where there are uncontaminated parts of the identified property, they may not be, strictly speaking, part of the ''site''). The ''site'' is thus neither equal to, nor confined by, the boundaries of any specific property that may give the site its name, and the name itself should not be read to imply that this site is coextensive with the entire area within the property boundary of the installation or plant. In addition, the site name is merely used to help identify the geographic location of the contamination, and is not meant to constitute any determination of liability at a site. For example, the name ''Jones Co. plant site,'' does not imply that the Jones Company is responsible for the contamination located on the plant site.

EPA regulations provide that the remedial investigation (''RI'') ''is a process undertaken. . .to determine the nature and extent of the problem presented by the release'' as more information is developed on site contamination, and which is generally performed in an interactive fashion with the feasibility study (''FS'') (40 CFR 300.5). During the RI/FS process, the release may be found to be larger or smaller than was originally thought, as more is learned about the source(s) and the migration of the contamination. However, the HRS inquiry focuses on an evaluation of the threat posed and therefore the boundaries of the release need not be exactly defined. Moreover, it generally is impossible to discover the full extent of where the contamination ''has come to be located'' before all necessary studies and remedial work are completed at a site. Indeed, the known boundaries of the contamination can be expected to change over time. Thus, in most cases, it may be impossible to describe the boundaries of a release with absolute certainty.

Further, as noted previously, NPL listing does not assign liability to any party or to the owner of any specific property. Thus, if a party does not believe it is liable for releases on discrete parcels of property, it can submit supporting information to the agency at any time after it receives notice it is a potentially responsible party.

For these reasons, the NPL need not be amended as further research reveals more information about the location of the contamination or release.

G. How are sites removed from the NPL?

The EPA may delete sites from the NPL where no further response is appropriate under Superfund, as explained in the NCP at 40 CFR 300.425(e). This section also provides that the EPA shall consult with states on proposed deletions and shall consider whether any of the following criteria have been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required;

(ii) All appropriate Superfund-financed response has been implemented and no further response action is required; or

(iii) The remedial investigation has shown the release poses no significant threat to public health or the environment, and taking of remedial measures is not appropriate.

H. May the EPA delete portions of sites from the NPL as they are cleaned up?

In November 1995, the EPA initiated a policy to delete portions of NPL sites where cleanup is complete (60 FR 55465, November 1, 1995). Total site cleanup may take many years, while portions of the site may have been cleaned up and made available for productive use.

I. What is the Construction Completion List (CCL)?

The EPA also has developed an NPL construction completion list (''CCL'') to simplify its system of categorizing sites and to better communicate the successful completion of cleanup activities (58 FR 12142, March 2, 1993). Inclusion of a site on the CCL has no legal significance.

Sites qualify for the CCL when: (1) Any necessary physical construction is complete, whether or not final cleanup levels or other requirements have been achieved; (2) the EPA has determined that the response action should be limited to measures that do not involve construction (*e.g.,* institutional controls); or (3) the site qualifies for deletion from the NPL. For more information on the CCL, see the EPA's internet site at *https://www.epa.gov/superfund/construction-completions-national-priorities-list-npl-sites-number.*

J. What is the Sitewide Ready for Anticipated Use measure?

The Sitewide Ready for Anticipated Use measure represents important Superfund accomplishments and the measure reflects the high priority the EPA places on considering anticipated future land use as part of the remedy selection process. See Guidance for Implementing the Sitewide Ready-for-Reuse Measure, May 24, 2006, OSWER 9365.0–36. This measure applies to final and deleted sites where construction is complete, all cleanup goals have been achieved, and all institutional or other controls are in place. The EPA has been successful on many occasions in carrying out remedial actions that ensure protectiveness of human health and the environment for current and future land uses, in a manner that allows contaminated properties to be restored to environmental and economic vitality. For further information, please go to *https://www.epa.gov/superfund/about-superfund-cleanup-process#tab-9.*

K. What is state/tribal correspondence concerning NPL listing?

In order to maintain close coordination with states and tribes in the NPL listing decision process, the EPA's policy is to determine the position of the states and tribes regarding sites that the EPA is considering for listing. This consultation process is outlined in two memoranda that can be found at the following website: *https://www.epa.gov/superfund/statetribal-correspondence-concerning-npl-site-listing.*

The EPA has improved the transparency of the process by which state and tribal input is solicited. The EPA is using the Web and where appropriate more structured state and tribal correspondence that (1) explains the concerns at the site and the EPA's rationale for proceeding; (2) requests an explanation of how the state intends to address the site if placement on the NPL is not favored; and (3) emphasizes the

transparent nature of the process by informing states that information on their responses will be publicly available.

A model letter and correspondence between the EPA and states and tribes where applicable, is available on the EPA's website at *http://semspub.epa.gov/src/document/HQ/174024.*

II. Availability of Information to the Public

A. May I review the documents relevant to this final rule?

Yes, documents relating to the evaluation and scoring of the sites in this final rule are contained in dockets located both at the EPA headquarters and in the EPA regional offices.

An electronic version of the public docket is available through *https://www.regulations.gov* (see table below for docket identification numbers). Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facilities identified in section II.D.

DOCKET IDENTIFICATION NUMBERS BY SITE

Site name	City/county, state	Docket ID No.
Schroud Property	Chicago, IL	EPA–HQ–OLEM–2019–0077.
Arsenic Mine	Kent, NY	EPA–HQ–OLEM–2019–0078.

B. What documents are available for review at the EPA Headquarters docket?

The headquarters docket for this rule contains the HRS score sheets, the documentation record describing the information used to compute the score, a list of documents referenced in the documentation record for each site and any other information used to support the NPL listing of the site.

C. What documents are available for review at the EPA regional dockets?

The EPA regional dockets contain all the information in the headquarters docket, plus the actual reference documents containing the data principally relied upon by the EPA in calculating or evaluating the HRS score. These reference documents are available only in the regional dockets.

D. How do I access the documents?

You may view the documents, by appointment only, after the publication of this rule. The hours of operation for the headquarters docket are from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. Please contact the regional dockets for hours. For addresses for the headquarters and regional dockets, see **ADDRESSES** section in the beginning portion of this preamble.

E. How may I obtain a current list of NPL sites?

You may obtain a current list of NPL sites via the internet at *https://www.epa.gov/superfund/national-priorities-list-npl-sites-site-name* or by contacting the Superfund docket (see contact information in the beginning portion of this document).

III. Contents of This Final Rule

A. Additions to the NPL

This final rule adds the following two sites to the General Superfund section of the NPL. Schroud Property is being added to the NPL based on an HRS score of 28.50 or above. Arsenic Mine is being added based on ATSDR health advisory criteria.

GENERAL SUPERFUND SECTION

State	Site name	City/county
IL	Schroud Property	Chicago.
NY	Arsenic Mine	Kent.

B. What did the EPA do with the public comments it received?

The EPA reviewed all comments received on the sites in this rule and responded to all relevant comments. The EPA is adding two sites to the NPL in this final rule. The sites were proposed for addition to the NPL on June 3, 2109 (84 FR 25509).

The EPA received one unrelated comment on the Arsenic Mine site.

The EPA received comments from 21 comment submitters that expressed support for the proposed addition of the Schroud Property site. While all of the comments received were in support of placing the Schroud Property site on the NPL, some comments expressed additional concerns. These concerns include:

- Scoring or investigating additional pathways and threats such as contaminant movement via air and groundwater in the HRS documentation record and threats from electric arc furnace (EAF) dust (specifically zinc and lead) in the HRS evaluation
- Environmental justice concerns including nearby minority populations and economically disadvantaged neighborhoods, and associated economic impacts
- Lack of institutional/physical barriers to limit access the property
- Questions on the prioritizing of funding and cleanup
- General concerns of site contaminant effects on human health, fishing, and nearby sensitive species and habitats
- Possible future remedial techniques

Regarding comments in support of NPL listing that recommend scoring additional HRS pathways, threats and contaminants (*i.e.,* the EAF dust) at the Schroud Property site, the HRS does not require that a site be evaluated for all possible migration and exposure pathways or all contaminants before the HRS evaluation is completed. Evaluation and scoring of these pathways in the HRS documentation record could only result in an increased HRS score and, thus, would not have any impact on the eligibility of the site for the NPL. Although the EPA did not score other pathways, this does not mean that there is no associated concern or that the EPA will not investigate other pathways in the future. The HRS is a screening model that uses limited resources to determine whether a site should be placed on the NPL for possible Superfund response. A subsequent stage of the Superfund process, the remedial investigation (RI), characterizes conditions and hazards at the site more comprehensively. Through the RI process, the EPA will fully characterize the risks to human health and the environment from contamination at the site, determine what cleanup is needed, and select an appropriate remedy with input from the community.

Many sites on the NPL are located in environmental justice, minority and/or poor communities. Through the cleanup of these sites, the Superfund program has sought to ensure that residents do not bear a disproportionate share of the negative environmental consequences resulting from past industrial, governmental, and commercial operations, and that they have meaningful involvement in the decisions on how to clean up the site.

The EPA is working with the city of Chicago to increase security and control access to the site. In April 2019, the city placed twenty-seven, 5,000-pound barriers around the property at access points to limit and discourage trespassing on the property. The EPA will continue to work with the community and the city of Chicago throughout the later stages of the superfund process to restrict access to the site.

IV. Statutory and Executive Order Reviews

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

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

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

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

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

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This rule does not contain any information collection requirements that require approval of the OMB.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This rule listing sites on the NPL does not impose any obligations on any group, including small entities. This rule also does not establish standards or requirements that any small entity must meet, and imposes no direct costs on any small entity. Whether an entity, small or otherwise, is liable for response costs for a release of hazardous substances depends on whether that entity is liable under CERCLA 107(a). Any such liability exists regardless of whether the site is listed on the NPL through this rulemaking.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments or the private sector. Listing a site on the NPL does not itself impose any costs. Listing does not mean that the EPA necessarily will undertake remedial action. Nor does listing require any action by a private party, state, local or tribal governments or determine liability for response costs. Costs that arise out of site responses result from future site-specific decisions regarding what actions to take, not directly from the act of placing a site on the NPL.

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. Listing a site on the NPL does not impose any costs on a tribe or require a tribe to take remedial action. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because this action itself is procedural in nature (adds sites to a list) and does not, in and of itself, provide protection from environmental health and safety risks. Separate future regulatory actions are required for mitigation of environmental health and safety risks.

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

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

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations because it does not affect the level of protection provided to human health or the environment. As discussed in Section I.C. of the preamble to this action, the NPL is a list of national priorities. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is of only limited significance as it does not assign liability to any party. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

L. Congressional Review Act

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

Provisions of the Congressional Review Act (CRA) or section 305 of CERCLA may alter the effective date of this regulation. Under 5 U.S.C. 801(b)(1), a rule shall not take effect, or continue in effect, if Congress enacts (and the President signs) a joint resolution of disapproval, described under section 802. Another statutory provision that may affect this rule is CERCLA section 305, which provides for a legislative veto of regulations promulgated under CERCLA. Although *INS* v. *Chadha,* 462 U.S. 919,103 S. Ct. 2764 (1983), and *Bd. of Regents of the University of Washington* v. *EPA,* 86 F.3d 1214,1222 (D.C. Cir. 1996), cast the validity of the legislative veto into question, the EPA has transmitted a copy of this regulation to the Secretary of the Senate and the Clerk of the House of Representatives.

If action by Congress under either the CRA or CERCLA section 305 calls the effective date of this regulation into question, the EPA will publish a document of clarification in the **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: October 28, 2019.

Peter C. Wright,

Assistant Administrator, Office of Land and Emergency Management.

For the reasons set out in the preamble, title 40, chapter I, part 300, of the Code of Federal Regulations is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p.193.

■ 2. Table 1 of appendix B to part 300 is amended by adding the entries for ''IL, Schroud Property, Chicago'', and ''NY, Arsenic Mine, Kent'' in alphabetical order by state and site name to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes [a]
*	* * * * * * *		
IL	Schroud Property	Chicago	
*	* * * * * * *		
NY	Arsenic Mine	Kent	A
*	* * * * * * *		

[a] A = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

* * * * *

[FR Doc. 2019–24151 Filed 11–6–19; 4:15 pm]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130312235–3658–02; RTID 0648–XS015]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Resources of the South Atlantic; Vermilion Snapper Trip Limit Reduction

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

ACTION: Temporary rule; trip limit reduction.

SUMMARY: NMFS reduces the commercial trip limit for vermilion snapper in or from the exclusive economic zone (EEZ) of the South Atlantic to 500 lb (227 kg), gutted weight, 555 lb (252 kg), round weight. This trip limit reduction is necessary to protect the South Atlantic vermilion snapper resource.

DATES: This rule is effective 12:01 a.m., local time, November 11, 2019, until 12:01 a.m., local time, January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Frank Helies, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *frank.helies@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery in the South Atlantic includes vermilion snapper and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The South Atlantic Fishery Management Council prepared the FMP. The FMP is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The commercial ACL (commercial quota) for vermilion snapper in the South Atlantic is divided into two 6-month seasons, January through June, and July through December. For the July 1 through December 31, 2019, fishing season, the commercial quota is 483,658 lb (219,384 kg), gutted weight; 536,860 lb (243,516 kg), round weight (50 CFR 622.190(a)(4)(ii)(A)). As specified in 50 CFR 622.190(a)(4)(iii), any unused portion of the commercial quota from the January through June 2019, fishing season will be added to the commercial quota for the July through December 2019, fishing season. The unused portion of the quota that was not harvested by the commercial sector during the January through June fishing season, totaled 25,645 lb (11,632 kg) gutted weight, 28,466 lb (12,912 kg), round weight, and was added to the July through December 2019 quota. This resulted in an adjusted commercial quota, for the July through December 2019 fishing season, of 509,303 lb (231,015 kg), gutted weight, 565,326 lb (256,428 kg), round weight.

Under 50 CFR 622.191(a)(6)(ii), NMFS is required to reduce the commercial trip limit for vermilion snapper from 1,000 lb (454 kg), gutted weight, 1,110 lb (503 kg), round weight, to 500 lb (227 kg), gutted weight, 555 lb (252 kg), round weight, when 75 percent of the fishing season commercial quota is reached or projected to be reached, by filing a notification to that effect with the Office of the Federal Register. Based on current landings information, NMFS has determined that 75 percent of the available adjusted commercial quota for the July through December 2019 fishing season for vermilion snapper will be reached by November 11, 2019. Accordingly, NMFS is reducing the commercial trip limit for vermilion snapper to 500 lb (227 kg), gutted weight, 555 lb (252 kg), round weight, in or from the South Atlantic EEZ at 12:01 a.m., local time, on November 11, 2019. This reduced commercial trip limit will remain in effect until the start of the next commercial fishing season on January 1, 2020, or until the adjusted commercial quota is reached and the commercial sector closes, whichever occurs first.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of South Atlantic vermilion snapper and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.191(a)(6)(ii) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds that the need to immediately implement this commercial trip limit reduction constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), because prior notice and opportunity for public comment on this temporary rule is unnecessary and contrary to the public interest. Such procedures are unnecessary, because the rule establishing the trip limit has already been subject to notice and comment, and all that remains is to notify the public of the trip limit reduction. Prior notice and opportunity for public comment is contrary to the public interest, because any delay in reducing the commercial trip limit could result in the commercial quota being exceeded. There is a need to immediately implement this action to protect the vermilion snapper resource, since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment on this action would require time and increase the probability that the commercial sector could exceed its quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 5, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–24410 Filed 11–5–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 217
Friday, November 8, 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 AGRICULTURE

Office of the Secretary

5 CFR Part 8301

[Docket No. USDA–2019–0005]

RIN 3209–AA48

Supplemental Standards of Ethical Conduct for Employees of the Department of Agriculture

AGENCY: Department of Agriculture, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Agriculture (''USDA'' or ''Department''), with the concurrence of the U.S. Office of Government Ethics (OGE), is issuing this proposed rule for attorneys of USDA's Office of the General Counsel (OGC). This proposed rule further supplements the Standards of Ethical Conduct for Employees of the Executive Branch (OGE Standards) issued by OGE by revising USDA's existing supplemental regulation concerning the outside practice of law by USDA OGC attorneys. The current regulation requires OGC attorneys to obtain written approval before engaging in the outside practice of law. To more fully address ethical issues unique to OGC attorneys, the proposed revision retains this prior approval requirement and imposes additional restrictions on the outside practice of law, subject to certain exceptions.

DATES: The comment period will be open for 45 calendar days. Written comments are invited and must be received on or before December 23, 2019.

ADDRESSES: You may submit comments, identified by Docket No. USDA–2019–0005 or the Regulatory Information Number (RIN) 3209–AA48, by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FederalRegisterComments@usda.gov.* Include Docket No. USDA–2019–0005 or RIN number 3209–AA48 in the subject line of the message.
- *Mail, Hand Delivery, or Courier:* Office of the Executive Secretary, USDA Whitten Federal Building Room 116–A, 1400 Independence Avenue SW, Washington, DC 20250.

Instructions: All submissions must include the agency name and docket number RIN number for this rulemaking. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at Room 347–W, J.L. Whitten Federal Building, 1400 Independence Avenue SW, Washington, DC 20250, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect the documents by telephoning (202) 720–2251.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or social security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Stuart Bender, Director of the Office of Ethics, U.S. Department of Agriculture, at (202) 720–2251, *Stuart.Bender@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

On August 7, 1992, OGE published the OGE Standards. See 57 FR 35006–35067, as corrected at 57 FR 48557, 57 FR 52483, and 60 FR 51167. The OGE Standards, codified at 5 CFR part 2635, effective February 3, 1993, established uniform standards of ethical conduct that apply to all executive branch personnel.

Pursuant to 5 CFR 2635.105, executive branch agencies are authorized to publish, with the concurrence of OGE, agency-specific supplemental regulations that are deemed necessary to properly implement their respective ethics programs. On March 24, 2000, USDA, with OGE's concurrence, published in the **Federal Register** an interim final rule to establish the USDA Supplemental Ethics Regulations. 65 FR 15825. The regulation was finalized on October 2, 2000 (65 FR 58635). USDA, with OGE's concurrence, now proposes to amend the USDA Supplemental Ethics Regulations as they relate to OGC attorneys that engage in the outside practice of law.

Summary of Proposed Changes

Section 8301.105 Additional Rules for Attorneys in the Office of the General Counsel

Summary

USDA can, and does, take actions every day that affect enterprises as diverse as farm and ranch production, food safety inspections and the grading of commodities, environmental protection and forest land use, import and export of agricultural products, grocery retailers and supplemental nutrition assistance programs, the national school lunch program, soil conservation, wildfire control, rural development and infrastructure rebuilding, and promoting the expansion of foreign markets for agricultural commodity exports. In view of the pervasiveness and variety of USDA-regulated and USDA-affected businesses and organizations in the United States, there is a significant risk that OGC attorneys engaged in the outside practice of law may increasingly confront actual or apparent conflicts of interest. USDA therefore proposes to update § 8301.105, which currently requires prior approval for the outside practice of law, to include certain additional restrictions and accompanying exceptions.

Because OGC engages in a wide range of litigation, enforcement, transactional, advisory and regulatory functions across the Department and the nation's agriculture sector, strengthening the requirements for compliance with ethical restrictions is necessary to ensure that a reasonable person will not question the integrity of the OGC attorneys who play an essential role in the Department's programs and operations. OGC would be hindered in fulfilling its mission if members of the public did not have confidence in the ability of its attorneys to act impartially while performing their official duties.

Analysis of the Regulation

Paragraph (a) requires OGC attorneys to obtain prior written approval before

engaging in the ''outside practice of law,'' as it is defined in that paragraph. OGC attorneys must obtain the approval in accordance with the existing procedures described in § 8301.102(c) and the standard for approval in paragraph (b).

Paragraph (b) sets out the standard to be applied in reviewing requests for prior approval for the outside practice of law. Approval will be granted unless it is determined that the outside practice of law is expected to involve conduct prohibited by statute, Federal regulations, including the OGE Standards, or paragraph (c) of this supplemental regulation. This standard is consistent with the standard for approval in § 8301.102(d).

Paragraph (c)(1) prohibits OGC attorneys from engaging in the outside practice of law where the activity, in fact or in appearance, may require the assertion of a legal position that conflicts with the interests of the Department. OGC attorneys are also prohibited from engaging in any outside law practice that might require the interpretation of a statute, regulation, or rule administered or issued by the Department. Attorneys in OGC are also prohibited from engaging in any outside practice of law where a supervisory attorney determines that such outside practice of law would conflict with the employee's official duties or create the appearance of a loss of the attorney's impartiality as prohibited by 5 CFR 2635.802. Further, as prohibited by 18 U.S.C. 205, OGC attorneys may not act as an agent or attorney in any matter in which the U.S. Government is a party or has a direct and substantial interest. Paragraph (c)(2) enunciates certain exceptions from the prohibitions listed in paragraph (c)(1). Paragraph (c)(3) outlines the procedures for the use of those exceptions.

Asserting Contrary Legal Positions

Paragraph (c)(1)(i) is consistent with the rules of professional conduct governing the attorney-client relationship. Precluding any outside law practice that may require the assertion of legal positions adverse to the Department derives from the unique and sensitive relationship between an attorney and a client, which for OGC attorneys is USDA.

Moreover, the Department has a legitimate interest in maintaining the consistency and credibility of the Department's positions before the Federal courts. For the most part, the representational bans contained in 18 U.S.C. 203 and 205 would preclude outside practice by OGC attorneys in the Federal courts because nondiversity cases within Federal court jurisdiction generally involve controversies in which the United States is a party or has a direct and substantial interest. However, cases may arise involving the interpretation or application of Federal statutes or regulations that do not necessarily implicate the direct and substantial interests of the United States.

As a consequence, OGC attorneys representing private clients might appear in front of the same judges before whom they appear in their official capacities and argue different interpretations of Federal statutes or regulations. Depending upon the visibility of the issues and any attendant controversy, asserting conflicting legal positions may diminish the persuasiveness of the advocate, erode judicial confidence in the integrity of the Department's attorneys, and undermine the credibility of both clients. Section 8301.105(c)(1)(i) is intended, therefore, to safeguard the interests of the Department as the primary client to which the attorney employee owes a professional responsibility.

Concededly, while representing a private client, an OGC attorney might take legal positions on a myriad of issues not directly related to Federal interests or agency programs—such as jurisdiction, service of process, standing, evidence, or statutory construction—that differ from those the attorney might have asserted while acting in a Government capacity. The section is not intended to proscribe instances of outside practice merely because such issues would have been handled differently if the matters arose in the prosecution or defense of an agency case. Generally, advocacy with respect to ancillary issues unrelated to substantive legal positions or agency administered statutes would be unlikely to have an impact sufficiently adverse to agency interest to be proscribed by the regulation.

Interpreting Department of Agriculture Administered Statutes

Paragraph (c)(1)(ii) is intended to effectuate the prohibition on the use of public office for private gain, to preclude inconsistent legal positions on core issues affecting the interests of the Department, and to protect the public interest by preventing any public perception that an attorney's employment with the Department signifies extraordinary competency on agency related issues, or that an OGC attorney's interpretation implicitly is sanctioned or approved by the Department. For the most part, outside practice involving agency-administered statutes would be precluded as a conflicting activity. If the subject matter of the proposed representation and the assigned duties of the attorney correlate, the outside activity potentially would require, under the standards set forth in 5 CFR 2635.402 and 2635.502, the employee's disqualification from matters so central or critical to the performance of the employee's official duties that the employee's ability to perform the duties of the employee's position would be materially impaired. Similarly, representation on matters involving the application of agency statutes may implicate direct and substantial interests of the United States, thus contravening the representational bans in 18 U.S.C. 203 and 205.

Although the regulation to some extent covers areas that are subject to existing prohibitions, paragraph (c)(1)(ii) reaches situations not specifically addressed in the existing standards. Absent the prohibition contained in this section, an OGC attorney principally engaged in advising a USDA Mission Area or Secretarial Staff Office conceivably could obtain outside employment advising, as opposed to representing, a private client on areas of agency law to which the attorney is not assigned. In these circumstances, there is considerable risk that the outside legal employment position held by the individual may convey an impression of authoritativeness or access to non-public information or agency experts that may not necessarily be warranted. Moreover, private clients, and those aware of the OGC attorney's involvement, may assume incorrectly that the attorney's interpretation has been vetted through the Department and is effectively a Departmental interpretation as well. Rendering legal services that may require the interpretation of any statute, regulation, or rule administered or issued by the Department creates an appearance that the employee has used the employee's official position to obtain an outside business opportunity. Further, if counsel were engaged in the outside law practice that involved Department statutes, the potential risk for asserting legal positions adverse to the interests of the Department would be heightened. Similarly, as established at 5 CFR 2635.802(b), it would undermine the effectiveness of the attorney and the attorney's duty of loyalty to the Department in those situations where a supervisory attorney determined that the outside practice of law would create

a conflict of interest, or the appearance of a loss of impartiality, requiring the attorney's disqualification from matters central to the attorney's performance of his official duties. In such situations, the attorney's duty of loyalty to the Department as the attorney's primary client must take first priority.

Acting as an Agent

Paragraph (c)(1)(iii) highlights the proscription in 18 U.S.C. 205 barring employees from acting as an agent or attorney in any matter in which the United States Government is a party or where the Government has a direct and substantial interest.

Exceptions

Paragraph (c)(2) provides exceptions to the prohibitions set forth in paragraph (c)(1). Consistent with the exceptions to the representational bans contained in 18 U.S.C. 203 and 205, nothing in this regulation precludes representation, if approved in advance by the appropriate official or supervisor, that is: (1) Rendered, with or without compensation, to specified relatives or an estate for which an employee serves as a fiduciary; or (2) provided, without compensation, to an employee subject to disciplinary, loyalty, or other personnel administration proceedings; or (3) rendered, without compensation to a voluntary employee nonprofit organization or group (such as child care centers, recreational associations, professional organizations, credit unions or other similar groups) before the U.S. Government under certain circumstances (18 U.S.C. 205 restricts employees from representing an employee organization or group in claims against the Government, in seeking grants, contracts or funds from the Government, or in a judicial or administrative proceeding where the organization or group is a party). Moreover, paragraph (c)(2)(iv) makes explicit that neither the ban on asserting contrary positions nor the prohibition on interpreting agency statutes is intended to proscribe the giving of testimony under oath. In order to take advantage of the exceptions to 18 U.S.C. 203 and 205 for representing family members or an estate, both statutes expressly require the approval of the Government official responsible for the employee's appointment. See 18 U.S.C. 203(d) and 205(e). To take advantage of the other exceptions set forth in paragraph (c)(2), the employee's supervisor must determine that the representations are not ''inconsistent with the faithful performance of [the employee's] duties.'' See 18 U.S.C. 205(d). These approval procedures are detailed in paragraph (c)(3).

Pro Bono

Paragraph (d) permits attorneys in OGC, subject to the restrictions in paragraph (c)(1), to provide outside *pro bono* legal services to organizations or individuals through a non-profit organization, without obtaining prior written approval. For example, Department attorneys may provide legal services *pro bono publico* in areas such as drafting wills or powers of attorney, assisting the preparation of domestic violence protective orders, and landlord-tenant disputes. These *pro bono* activities can generally be undertaken without detriment to the Department's interests, provided that the employee adheres to the limitations of this rule. The Department encourages such volunteer legal activities, if not inconsistent with this supplemental regulation and the laws and regulations described above. Attorneys in the OGC who have questions about whether a specific *pro bono* legal service would comply with the limitations of this rule are encouraged to seek advance guidance from USDA's Office of Ethics.

Matters of Regulatory Procedure

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (the RFA), requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations, unless the head of the agency certifies that the rules will not have a significant economic impact on a substantial number of small entities. The Secretary of Agriculture so certifies. The rule does not impose any obligations or standards of conduct for purposes of analysis under the RFA, and it therefore does not give rise to a regulatory compliance burden for small entities.

Paperwork Reduction Act

The Department has determined that this rule does not impose any new recordkeeping, reporting, or disclosure requirements on members of the public that would be collections of information requiring approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 5 CFR Part 8301

Conflict of interests, Government employees.

Authority and Issuance

For the reasons set forth in the preamble, the Department is proposing to amend 5 CFR part 8301 as follows:

PART 8301—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF AGRICULTURE

■ 1. The authority citation for part 8301 is revised to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. App.; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.403, 2635.502 and 2635.803.

■ 2. Revise § 8301.105 to read as follows:

§ 8301.105 Additional rules for attorneys in the Office of the General Counsel.

(a) *Additional rules for attorneys in the Office of the General Counsel regarding the outside practice of law.* Any attorney serving within the Office of the General Counsel shall obtain written approval, in accordance with the procedures set forth in § 8301.102(c) and the standard for approval set forth in paragraph (b) of this section, before engaging in the outside practice of law, whether compensated or not. For purposes of this section the ''outside practice of law'' means those activities requiring professional licensure by a state bar as an attorney and include, but are not limited to, providing legal advice to a client, drafting legal documents, and representing clients in legal negotiations or litigation.

(b) *Standard for approval.* Approval shall be granted by the agency designee unless it is determined that the outside practice of law is expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635, or paragraph (c) of this section.

(c) *Prohibited outside practice of law applicable to attorneys in the Office of the General Counsel*—(1) *General prohibitions.* An employee who serves as an attorney within the Office of the General Counsel shall not engage in any outside practice of law that might require the attorney to:

(i) Assert a legal position that is or appears to be in conflict with the interests of the Department of Agriculture, the client to which the attorney owes a professional responsibility; or

(ii) Interpret any statute, regulation, or rule administered or issued by the Department of Agriculture, or where a supervisory attorney determines that the outside practice of law would conflict with the employee's official duties or create the appearance of a loss of the

attorney's impartiality, as prohibited by 5 CFR 2635.802; or

(iii) Act as an agent or attorney in any matter in which the U.S. Government is a party or has a direct and substantial interest, as prohibited by 18 U.S.C. 205.

(2) *Exceptions.* Nothing in paragraph (c)(1) of this section prevents an attorney in the Office of the General Counsel from:

(i) Acting, with or without compensation, as an agent or attorney for, or otherwise representing, the employee's parents, spouse, child, or any other person for whom, or for any estate for which, the employee is serving as guardian, executor, administrator, trustee, or other personal fiduciary to the extent permitted by 18 U.S.C. 203(d) and 205(e), or from providing advice or counsel to such persons or estates; or

(ii) Acting, without compensation, as an agent or attorney for, or otherwise representing, any person who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings, or from providing uncompensated advice and counsel to such person to the extent permitted by 18 U.S.C. 205; or

(iii) Acting, without compensation, as an agent or attorney for, or otherwise representing any cooperative, voluntary, professional, recreational, or similar organization or group not established or operated for profit, if a majority of the organization's or group's members are current employees of the United States or the District of Columbia, or their spouses or dependent children. As limited by 18 U.S.C. 205(d), this exception is not permitted for any representation with respect to a matter which involves prosecuting a claim against the United States under 18 U.S.C. 205(a)(1) or (b)(1), or involves a judicial or administrative proceeding where the organization or group is a party, or involves a grant, contract, or other agreement providing for the disbursement of Federal funds to the organization or group; or

(iv) Giving testimony under oath or from making statements required to be made under penalty for perjury or contempt.

(3) *Specific approval procedures for paragraph (c)(2) of this section.* (i) The exceptions to 18 U.S.C. 203 and 205 described in paragraph (c)(2)(i) of this section do not apply unless the employee obtained the prior approval of the Government official responsible for the appointment of the employee to a Federal position.

(ii) The exception to 18 U.S.C. 205 described in paragraphs (c)(2)(ii) and (iii) of this section does not apply unless the employee has obtained the prior approval of a supervisory official who has authority to determine whether the employee's proposed representation is consistent with the faithful performance of the employee's duties.

(d) *Pro bono activity.* Subject to compliance with paragraph (c) of this section, attorneys within the Office of the General Counsel are permitted to provide outside *pro bono* legal services (without compensation other than reimbursement of expenses) to organizations or individuals through a non-profit organization, without obtaining prior written approval in accordance with the procedures set forth in § 8301.102(c).

Stephen Alexander Vaden,

General Counsel, U.S. Department of Agriculture.

In concurrence:

Emory A. Rounds, III,

Director, U.S. Office of Government Ethics.

[FR Doc. 2019–24082 Filed 11–7–19; 8:45 am]

BILLING CODE 3410–90–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0882; Product Identifier 2018–SW–113–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Airbus Helicopters Model AS332C, AS332C1, AS332L, and AS332L1 helicopters. This proposed AD would require inspecting the attachment screws of each main gearbox (MGB) suspension bar rear attachment fitting, and depending on the outcome, applying a sealing compound, performing further inspections, and replacing affected parts. This proposed AD is prompted by reports of an elongated attachment screw and loss of tightening torque of the nut. The actions of this proposed AD are intended to address an unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 7, 2020.

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

- *Federal eRulemaking Docket:* Go to *https://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0882; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views. The FAA also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments,

commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments that the FAA receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments received.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2018–0282, dated December 19, 2018 (EASA AD 2018–0282), to correct an unsafe condition for Airbus Helicopters (formerly Eurocopter, Eurocopter France, Aerospatiale) Model AS332C, AS332C1, AS332L, and AS332L1 helicopters, delivered to the first owner or customer before September 1, 2018, and with attachment screws part number (P/N) 330A22013520 installed with MGB right hand (RH) side rear attachment fitting P/N 330A22270207 and left hand (LH) side rear attachment fitting P/N 330A22270206 of the MGB suspension bars.

EASA advises that occurrences were reported of elongated attachment screws and loss of tightening torque of the nut installed on the affected part. EASA also advises that an investigation is ongoing to determine the root cause of this event. EASA states this condition could lead to structural failure of an MGB rear attachment fitting and possibly result in detachment of an MGB suspension bar. Accordingly, EASA AD 2018–0282 requires a one-time inspection of each attachment screw for the number of threads that protrude beyond its bolt and depending on the outcome, applying a sealing compound on the nuts, and convex and concave washers; measuring the height of the protruding threads; inspecting the tightening torque of the nuts; inspecting the upper and lower convex and concave washers; measuring and inspecting removed attachment screws; and replacing affected parts. EASA AD 2018–0282 also requires reporting information to Airbus Helicopters. EASA states EASA AD 2018–0282 is considered to be an interim action and further AD action may follow.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type designs.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin No. AS332–53.02.04, Revision 0, dated November 21, 2018 which specifies checking the number of threads that protrude beyond the bolt of the attachment screws on the RH and LH rear attachment fittings of the MGB. This service information also specifies a one-time inspection of the affected parts and depending on findings, accomplishment of applicable corrective actions.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Proposed AD Requirements

This proposed AD would require inspecting each screw on the RH and LH rear attachment by identifying the number of threads ''F'' that extend beyond the nut. If there are 2 or less threads on each affected part, or if there are 3 or more threads on any affected part with a thread height less than 5 mm (0.196 in), this proposed AD would require applying a sealing compound on the nuts, and convex and concave washers. If there are 3 or more threads on any affected part with a thread height of 5 mm (0.196 in) or more, this proposed AD would require removing the nut and inspecting the convex and concave washers for bent parts and corrosion. If any washers are bent or corroded, this proposed AD would require removing the washers from service. If the length ''L'' measurement of any attachment screw is greater than 59.3 mm (2.334 in), this proposed AD would require replacing the attachment fitting and the set of four screws.

Differences Between This Proposed AD and the EASA AD

The EASA AD requires the operator to perform a torque check and report the value to Airbus, whereas this proposed AD would not.

Interim Action

The FAA considers this proposed AD interim action. The design approval holder is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, the FAA might consider additional rulemaking.

Costs of Compliance

The FAA estimates that this proposed AD would affect 14 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour.

Inspecting the number of threads and applying a sealing compound would take about 3 work-hours for an estimated cost of $255 per helicopter and $3,570 for the U.S. fleet.

Replacing an attachment fitting and the set of four screws would take about 16 work-hours and parts would cost about $6,330 for an estimated replacement cost of $7,690.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866,

2. Will not affect intrastate aviation in Alaska, and

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

The FAA prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2019–0882; Product Identifier 2018–SW–113–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS332C, AS332C1, AS332L, and AS332L1 helicopters, certificated in any category, delivered to the first owner or customer before September 1, 2018, and with attachment screws part number (P/N) 330A22013520 installed with main gearbox (MGB) right hand (RH) side rear attachment fitting P/N 330A22270207 and left hand (LH) side rear attachment fitting P/N 330A22270206 of the MGB suspension bars.

(b) Unsafe Condition

This AD defines the unsafe condition as elongation of the attachment screws and loss of tightening torque of the nut. This condition could result in structural failure of an MGB attachment fitting, detachment of an MGB suspension bar, and subsequent loss of control of the helicopter.

(c) Comments Due Date

The FAA must receive comments by January 7, 2020.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 110 hours time-in-service, remove the sealing compound and inspect each screw on the RH and LH rear attachment fitting by identifying the number of threads ''F'' that extend beyond the nut as shown in Detail ''B'' of Figure 2 of Airbus Helicopter Alert Service Bulletin No. AS332–53.02.04, Revision 0, dated November 21, 2018 (ASB AS332–53.02.04).

(1) If there are 2 or less threads on each of the four screws; or there are 3 or more threads on any screw with a thread height ''H'' less than 5 mm (0.196 in), before further flight, apply a sealing compound on the nuts, and convex and concave washers.

(2) If there are 3 or more threads on any screw with a thread height ''H'' of 5 mm (0.196 in) or more, before further flight, do the following, and for more than one screw, do one at a time while working in a cross pattern: Remove from service the nut; and remove the screw from the helicopter and measure the length ''L'' of the screw as shown in Detail ''D'' of Figure 2 of ASB AS332–53.02.04.

(i) If any washers are bent or corroded, before further flight, remove from service the washers.

(ii) If the length ''L'' measurement is less than or equal to 59.3 mm (2.334 in) for each screw removed as required by paragraph (e)(2) of this AD, visually inspect the screw for corrosion and cracks.

(A) For each screw with corrosion or a crack, before further flight, replace the screw with an airworthy screw.

(B) For any screw with no corrosion or cracks, before further flight, re-install the screw and washers. Install a new nut and apply sealant.

(iii) If the length ''L'' measurement is greater than 59.3 mm (2.334 in) for any screw removed as required by paragraph (e)(2) of this AD, before further flight, replace the rear attachment fitting that the screw was removed from and its set of four screws, washers, and nuts, and apply sealant as shown in Figures 2 and 3 of ASB AS332–53.02.04.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2018–0282, dated December 19, 2018. You may view the EASA AD on the internet at *https://www.regulations.gov* in the AD Docket.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6320, Main Rotor Gearbox.

Issued in Fort Worth, Texas, on October 31, 2019.

Helene T. Gandy,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019–24342 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0859; Product Identifier 2019–NM–114–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes. This proposed AD results from fuel system reviews conducted by the manufacturer. This proposed AD would require replacement of the bonding jumpers on the auxiliary power unit (APU) fuel pump. This proposed AD would also require, for certain airplanes, installation of a second bonding jumper; an inspection of the override/jettison fuel pumps and transfer/jettison fuel pumps to determine if the bonding jumper has a one-piece braid or two-piece braid and replacement of the bonding jumper if necessary; and replacement of the bonding jumper on the electrical scavenge fuel pump. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 23, 2019.

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

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–

30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0859.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0859; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jeffrey Rothman, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3558; email: *jeffrey.rothman@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2019–0859; Product Identifier 2019–NM–114–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

The FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this NPRM.

Discussion

The FAA has examined the underlying safety issues involved in fuel tank explosions on several large transport airplanes, including the adequacy of existing regulations, the service history of airplanes subject to those regulations, and existing maintenance practices for fuel tank systems. As a result of those findings, the FAA issued a final rule titled ''Transport Airplane Fuel Tank System Design Review, Flammability Reduction, and Maintenance and Inspection Requirements'' (66 FR 23086, May 7, 2001). In addition to new airworthiness standards for transport airplanes and new maintenance requirements, that rule included Amendment 21–78, which established Special Federal Aviation Regulation No. 88 (''SFAR 88'') at 14 CFR part 21. Subsequently, SFAR 88 was amended by Amendment 21–82 (67 FR 57490, September 10, 2002; corrected at 67 FR 70809, November 26, 2002) and Amendment 21–83 (67 FR 72830, December 9, 2002; corrected at 68 FR 37735, June 25, 2003, to change ''21–82'' to ''21–83'').

Among other actions, SFAR 88 requires certain type design (*i.e.,* type certificate (TC) and supplemental type certificate (STC)) holders to substantiate that their fuel tank systems can prevent ignition sources in the fuel tanks. This requirement applies to type design holders for large turbine-powered transport airplanes and for subsequent modifications to those airplanes. It requires them to perform design reviews and to develop design changes and maintenance procedures if their designs do not meet the new fuel tank safety standards. As explained in the preamble to the final rule published on May 7, 2001, the FAA intended to adopt airworthiness directives to mandate any changes found necessary to address unsafe conditions identified as a result of these reviews.

In evaluating these design reviews, the FAA has established four criteria intended to define the unsafe conditions associated with fuel tank systems that require corrective actions. The percentage of operating time during which fuel tanks are exposed to flammable conditions is one of these criteria. The other three criteria address the failure types under evaluation: Single failures, single failures in combination with another latent condition(s), and in-service failure experience. For all four criteria, the evaluations included consideration of previous actions taken that may mitigate the need for further action.

The FAA has determined that the actions identified in this proposed AD are necessary to reduce the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

The FAA has received data from the fuel tank inspection program indicating that the existing bond path design provides insufficient bond resistance margin between the fuel pump motor/impeller and structure. In the event of a fuel pump electrical fault, this condition might cause arcs at the existing fuel pump/tank interfaces and an ignition of fuel vapor in the wing fuel tank, which could result in a fuel tank explosion.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Service Bulletin 747–28–2228, Revision 1, dated September 27, 2001. This service information describes procedures for a replacement of the bonding jumpers on the APU fuel pump; an inspection of the six override/jettison fuel pumps and of the two transfer/jettison fuel pumps to determine if the bonding jumper has a one-piece braid or two-piece braid, and replacement of the existing bonding jumper if the bonding jumper has a one-piece braid; installation of a second bonding jumper; and replacement of the bonding jumper on the electrical scavenge fuel pump.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Relevant Rulemaking

Boeing Service Bulletin 747–28–2228, Revision 1, dated September 27, 2001, identifies ''Boeing Service Bulletin 747–28–2033'' as a concurrent requirement for certain airplanes. Boeing Alert Service Bulletin 747–28A2033, Revision 1, dated December 18, 2003, is the appropriate source of service information for accomplishing the installation required by AD 2005–01–07, Amendment 39–13931 (70 FR 1336, January 7, 2005) (''AD 2005–01–07''). The compliance time for accomplishing the installation required by AD 2005–01–07 has already passed; therefore, it is not necessary to include Boeing Alert Service Bulletin 747–28A2033 as a concurrent requirement in this proposed AD. The FAA issued AD 2005–01–07 to

ensure adequate electrical bonding between the housing of each fuel pump and airplane structure outside the fuel tanks. Inadequate electrical bonding, in the event of a lightning strike or fuel pump electrical fault, could cause electrical arcing and ignition of fuel vapor in the wing fuel tank, which could result in a fuel tank explosion.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

The FAA estimates that this proposed AD affects 74 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement, Installation, and Inspection.	Up to 15 work-hours × $85 per hour = Up to $1,275.	Up to $2,000	Up to $3,275	Up to $242,350.

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. The FAA has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	Up to 6 work-hours × $85 per hour = Up to $510.	Up to $950	Up to $1,460.

Authority for This Rulemaking

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

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

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2019–0859; Product Identifier 2019–NM–114–AD.

(a) Comments Due Date

The FAA must receive comments by December 23, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes, certificated in any category, line numbers (L/Ns) 1 through 1229 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by fuel system reviews conducted by the manufacturer indicating that the existing bond path design

provides insufficient bond resistance margin between the fuel pump motor/impeller and structure. The FAA is issuing this AD to address insufficient bond resistance margin between the fuel pump motor/impeller and structure. In the event of a fuel pump electrical fault, this condition might cause arcs at the existing fuel pump/tank interfaces and an ignition of fuel vapor in the wing fuel tank, which could result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Definitions

For the purposes of this AD, the definitions specified in paragraphs (g)(1) through (4) of this AD apply.

(1) Group 1 airplanes: L/Ns 1 through 167 inclusive.

(2) Group 2 airplanes: L/Ns 168 through 971 inclusive.

(3) Group 3 airplanes: L/Ns 972 through 1161 inclusive.

(4) Group 4 airplanes: L/Ns 1162 through 1229 inclusive.

(h) Replacement, Installation, and Inspection

Within 60 months after the effective date of this AD, do the applicable actions specified in paragraphs (h)(1) through (4) of this AD, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–28–2228, Revision 1, dated September 27, 2001.

(1) For Groups 1, 2, and 3 airplanes: Do the actions specified in paragraphs (h)(1)(i) and (ii) of this AD.

(i) Do a general visual inspection of the six override/jettison fuel pumps to determine if the bonding jumper has a one-piece braid or two-piece braid. If the bonding jumper has a one-piece braid, within 60 months after the effective date of this AD, replace the existing bonding jumper.

(ii) Install a second bonding jumper.

(2) For Groups 1, 2 and 3 airplanes with horizontal stabilizer fuel tanks: Do the actions specified in paragraphs (h)(2)(i) and (ii) of this AD.

(i) Do a general visual inspection of the two transfer/jettison fuel pumps to determine if the bonding jumper has a one-piece braid or a two-piece braid. If the bonding jumper has a one-piece braid, within 60 months after the effective date of this AD, replace the existing bonding jumper.

(ii) Install a second bonding jumper.

(3) For all airplanes: Replace the bonding jumpers on the auxiliary power unit (APU) fuel pump.

(4) For Groups 1 and 2 airplanes: Replace the bonding jumper on the electrical scavenge fuel pump.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9–ANM-Seattle-ACO–AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Jeffrey Rothman, Aerospace Engineer, Propulsion Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3558; email: *jeffrey.rothman@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on October 29, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–24329 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0785; Airspace Docket No. 19–AEA–14]

Proposed Revocation of Class E Airspace; Grundy, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove Class E airspace at Grundy, VA, as Grundy Municipal Airport has been abandoned, and controlled airspace is no longer required. This action would enhance the safety and management of controlled airspace within the national airspace system.

DATES: Comments must be received on or before December 23, 2019.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; Telephone: (800) 647–5527, or (202) 366–9826.You must identify the Docket No. FAA–2019–0785; Airspace Docket No. 19–AEA–14, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave, College Park, GA 30337; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in Subtitle VII, part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would

remove Class E airspace extending upward from 700 feet above the surface at Grundy Municipal Airport, Grundy, VA, due to the closing of the airport.

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2019–0785 and Airspace Docket No. 19–AEA–14) and be submitted in triplicate to the DOT Docket Operations (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0785; Airspace Docket No. 19–AEA–14.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to remove Class E airspace extending upward from 700 feet above the surface at Grundy Municipal Airport, Grundy, VA, as the airport has closed. Therefore, the airspace is no longer necessary. This action would enhance the safety and management of controlled airspace within the national airspace system.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1.

The Class E airspace designation listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

AEA VA E5 Grundy, VA [Removed]

Issued in College Park, Georgia, on October 30, 2019.

Debra Hogan,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–24346 Filed 11–7–19; 8:45 am]

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Copyright Royalty Board

37 CFR Part 383

[Docket No. 19–CRB–0006–NSR (2021–2025) (NSS IV)]

Digital Performance Right in Sound Recordings and Ephemeral Recordings

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges are publishing for comment proposed regulations governing the rates and terms for the digital performances of sound recordings by new subscription services and for the making of ephemeral recordings necessary to facilitate those transmissions for the period commencing January 1, 2021, and ending on December 31, 2025.

DATES: Comments and objections, if any, are due no later than December 9, 2019.

ADDRESSES: You may submit comments and objections, identified by docket number 19–CRB–0006–NSR (2021–2025), by any of the following methods:

CRB's electronic filing application: Submit comments and objections online in eCRB at *https://app.crb.gov/.*

U.S. mail: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE, Washington, DC 20559–6000. Deliver to: Congressional Courier Acceptance Site, 2nd Street NE and D Street NE, Washington, DC; or

Hand delivery: Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE, Washington, DC 20559–6000.

Instructions: Parties unable to use eCRB must submit an original, two paper copies, and an electronic version on a CD. All submissions must include a reference to the Copyright Royalty Board and docket number (19–CRB–0006–NSR (2021–2025)), as well as the **Federal Register** citation for this proposed rule. All submissions will be posted without change to eCRB at *https://app.crb.gov/* including any personal information provided.

Docket: For access to the docket to read submitted background documents or comments, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at *https://app.crb.gov/* and search for docket number 19–CRB–000–NSR (2021–2025).

FOR FURTHER INFORMATION CONTACT: Anita Blaine, Program Specialist, by telephone at (202) 707–0078, or by email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On October 21, 2019, the Copyright Royalty Judges (Judges) received a joint motion from SoundExchange, Inc., and Sirius XM Inc. to adopt a settlement of their interests regarding the rates and terms for 2021–2025 for certain new subscription services (NSS).[1] Joint Motion to Adopt Settlement, Docket No. 19–CRB–0006–NSR (2021–2025). The parties request that the Judges adopt the settlement in its entirety as a settlement of rates and terms under Sections 112(e) and 114 of the Copyright Act for new subscription services of the type at issue in the captioned proceeding, *i.e.,* music services provided to residential subscribers as part of a cable or satellite television bundle subject to royalty rates and terms in 37 CFR part 383. Joint Motion at 1. SoundExchange represents sound recording copyright owners and performers. Sirius XM relies on the royalty rates and terms in 37 CFR part 383 for music programming it provides through the DiSH satellite television service. The parties believe that Sirius XM is the only provider of a Part 383 service participating in this proceeding. Joint Motion at 2. The Judges hereby publish the settlement and request comments from the public.

Section 114 of the Copyright Act, title 17 of the United States Code, provides a statutory license that allows for the public performance of sound recordings by means of a digital audio transmission by, among others, new subscription services. 17 U.S.C. 114(f)(1)(A). For purposes of the section 114 license, a new subscription service is a ''service that performs sound recordings by means of noninteractive subscription digital audio transmissions and that is not a preexisting subscription service or a preexisting satellite digital audio radio service.'' 17 U.S.C. 114(j)(8).

Services using the section 114 license may need to make one or more temporary or ''ephemeral'' copies of a sound recording to facilitate the transmission of that recording. The section 112 statutory license allows for the making of the necessary ephemeral reproductions. 17 U.S.C. 112(e).

Chapter 8 of the Copyright Act requires the Judges to conduct proceedings every five years to determine the rates and terms for the sections 114 and 112 statutory licenses. 17 U.S.C. 801(b)(1), 804(b)(3)(A). The current proceeding commenced in February 2019 for rates and terms that will become effective on January 1, 2021, and end on December 31, 2025. 84 FR 6021 (Feb. 25, 2019). SoundExchange and Sirius XM each submitted petitions to participate.

Statutory Timing of Adoption of Rates and Terms

Section 801(b)(7)(A) allows for the adoption of rates and terms negotiated by ''some or all of the participants in a proceeding at any time during the proceeding'' provided the parties submit the negotiated rates and terms to the Judges for approval.

The Judges must provide ''an opportunity to comment on the agreement'' to participants and non-participants in the rate proceeding who ''would be bound by the terms, rates, or other determination set by any agreement. . . .'' 17 U.S.C. 801(b)(7)(A)(i). Participants in the proceeding may also ''object to [the agreement's] adoption as a basis for statutory terms and rates.'' *Id.*

The Judges ''may decline to adopt the agreement as a basis for statutory terms and rates for participants that are not parties to the agreement,'' only ''if any participant [in the proceeding] objects to the agreement and the [Judges] conclude, based on the record before them if one exists, that the agreement does not provide a reasonable basis for setting statutory terms or rates,'' 17 U.S.C. 801(b)(7)(A)(ii), or where the negotiated agreement includes provisions that are contrary to the provisions of the applicable license(s) or otherwise contrary to statutory law. *See* Scope of the Copyright Royalty Judges Authority to Adopt Confidentiality Requirements upon Copyright Owners within a Voluntarily Negotiated License Agreement, 78 FR 47421, 47422 (Aug. 5, 2013), citing 74 FR 4537, 4540 (Jan. 26, 2009).

Proposed Adjustments to Rates and Terms

The settlement incorporates the same royalty rate structure presently set forth in 37 CFR part 383, with annual 3% increases in the per-subscriber fee during the coming rate period. The parties have also agreed that certain terms in Part 383 should be those finally determined in the *Web V* proceeding (Docket No. 19–CRB–0005–WR (2021–2025)), rather than those determined in

[1] ''David Powell d/b/a Circle of God Network Inc. [sic] has also requested to join the Joint Motion.'' Joint Motion at 1 n.1.

an SDARS (satellite radio and ''preexisting'' subscription services) proceeding because the parties will have an opportunity to litigate terms issues in *Web V,* and the *Web V* terms will be in effect for the same period as covered by this proceeding. In other respects, the settlement preserves the existing provisions of Part 383 with only minor updating. Joint Motion at 2.

The fact that the Settlement includes proposed terms that have not yet been established in the *Web V* proceeding may raise concern as to whether participants and non-participants in the rate proceeding who would be bound by the terms, rates, or other determination set by any agreement are properly afforded the aforementioned statutory opportunities to object or comment on the agreement. However, the Judges take notice that it is not inappropriate for agreements to incorporate and/or rely in part on events, facts or determinations that have not yet been established, *e.g.,* references to adjustments based on yet to be determined consumer price index measurements. The Judges are also mindful that Congress intended to facilitate and encourage settlement agreements. *See,* H.R. Rep. No. 108–408, at 24 and 30 (2002). Accordingly, objectors and commenters may knowingly and willingly choose to accept some uncertainty as to future settlement terms and a reference to an outside method for resolving the uncertain issues.

Therefore, the Judges publish the Settlement with the current understanding that doing so is in compliance with the statutory opportunities to object or comment on the agreement.

The public may comment and object to any or all of the proposed regulations contained in this notice.[2] Such comments and objections must be submitted no later than December 9, 2019.

List of Subjects in 37 CFR Part 383

Copyright, Sound recordings, Webcasters.

For the reasons set forth in the preamble, the Copyright Royalty Judges propose to amend 37 CFR part 383 as follows:

[2] The parties represent that SoundExchange, Sirius XM, and Mr. Powell, all of which have joined the Joint Motion, are the only parties that have filed petitions to participate in this proceeding and, therefore, ''there is no basis for the Judges not to adopt the Settlement as the statutory terms and rates under Section 112(e) and 114 for services relying on the royalty rates and terms in 37 CFR part 383.'' Joint Motion at 3.

PART 383—RATES AND TERMS FOR SUBSCRIPTION TRANSMISSIONS AND THE REPRODUCTION OF EMPHEMERAL RECORDINGS BY CERTAIN NEW SUBSCRIPTION SERVICES

■ 1. The authority citation for part 383 continues to read as follows:

Authority: 17 U.S.C. 112(e), 114, and 801(b)(1).

§ 383.1 [Amended]

■ 2. Amend § 383.1 paragraphs (a) and (c) by removing ''2016'' wherever it appears and adding in its place, ''2021'', and by removing ''2020'' wherever it appears and adding in its place, ''2025''.;

§ 383.3 [Amended]

■ 3. In § 383.3 amend by:

■ a. Revising paragraph (a) by removing the words ''statutory licenses'' and adding, in their place, the word ''License'';

■ b. Revising paragraphs (a)(1)(i) through (v);

■ c. Revising paragraph (a)(2)(i) through (v); and

■ d. Revising paragraph (c).

The revisions read as follows:

(a) * * *

(1) * * *

(i) 2021: $0.0208

(ii) 2022: $0.0214

(iii) 2023: $0.0221

(iv) 2024: $0.0227

(v) 2025: $0.0234

* * * * *

(2) * * *

(1) * * *

(i) 2021: $0.0346

(ii) 2022: $0.0356

(iii) 2023: $0.0367

(iv) 2024: $0.0378

(v) 2025: $0.0390

* * * * *

(c) *Allocation between ephemeral recordings fees and performance royalty fees.* The Collective must credit 5% of all royalty payments as royalty payment for Ephemeral Recordings and credit the remaining 95% to section 114 royalties. All Ephemeral Recordings that a Licensee makes which are necessary and commercially reasonable for making noninteractive digital transmissions through a Service are included in the 5%.

§ 383.4 [Amended]

■ 4. In § 383.4 amend paragraph (a) by:

■ a. Removing the words ''subscription transmissions'' and adding, in their place, the words ''Digital audio transmission'';

■ b. Removing the words ''preexisting satellite digital audio radio services'' and adding, in their place, the words ''Commercial Webcasters'';

■ c. Removing the words ''part 382, subpart B'' and adding, in their place, the words ''part 380, subpart A'';

■ d. Removing the years ''2013–2017'' and adding, in their place, the years ''2021–2025'';

■ e. Removing the words ''For purposes of this section'' and adding, in their place, the words ''For purposes of this part''.

Dated: November 1, 2019.

Jesse M. Feder,

Chief Copyright Royalty Judge.

[FR Doc. 2019–24271 Filed 11–7–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2019–0484, 0485, 0486, 0487 and 0488; FRL–10001–91–OLEM]

National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the agency'') in determining which sites warrant further investigation. These further investigations will allow the EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule proposes to add five sites to the General Superfund section of the NPL.

DATES: Comments regarding any of these proposed listings must be submitted

(postmarked) on or before January 7, 2020.

ADDRESSES: Identify the appropriate docket number from the table below.

DOCKET IDENTIFICATION NUMBERS BY SITE

Site name	City/county, state	Docket ID No.
Blades Groundwater	Blades, DE	EPA–HQ–OLEM–2019–0484.
Caney Residential Yards	Caney, KS	EPA–HQ–OLEM–2019–0485.
Highway 100 and County Road 3 Groundwater Plume	St. Louis Park and Edina, MN	EPA–HQ–OLEM–2019–0486.
Henryetta Iron and Metal	Henryetta, OK	EPA–HQ–OLEM–2019–0487.
Clearwater Finishing	Clearwater, SC	EPA–HQ–OLEM–2019–0488.

You may send comments, identified by the appropriate docket number, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Agency website: https://www.epa.gov/superfund/current-npl-updates-new-proposed-npl-sites-and-new-npl-sites.* Scroll down to the site for which you would like to submit comments and click the ''Comment Now'' link.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Superfund Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the appropriate Docket ID No. for site(s) for which you are submitting comments. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Review/Public Comment'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone: (703) 603–8852, email: *jeng.terry@epa.gov,* Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation, Mail code 5204P, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Public Review/Public Comment

A. May I review the documents relevant to this proposed rule?

Yes, documents that form the basis for the EPA's evaluation and scoring of the sites in this proposed rule are contained in public dockets located both at the EPA Headquarters in Washington, DC, and in the regional offices. These documents are also available by electronic access at *https://www.regulations.gov* (see instructions in the **ADDRESSES** section above).

B. How do I access the documents?

You may view the documents, by appointment only, in the Headquarters or the regional dockets after the publication of this proposed rule. The hours of operation for the Headquarters docket are from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding Federal holidays. Please contact the regional dockets for hours.

The following is the contact information for the EPA Headquarters Docket: Docket Coordinator, Headquarters, U.S. Environmental Protection Agency, Superfund (CERCLA) Docket Office, 1301 Constitution Avenue NW, William Jefferson Clinton Building West, Room 3334, Washington, DC 20004; 202/566–0276. (Please note this is a visiting address only. Mail comments to the EPA

Headquarters as detailed at the beginning of this preamble.)

The contact information for the regional dockets is as follows:

- Holly Inglis, Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA, Superfund Records and Information Center, 5 Post Office Square, Suite 100, Boston, MA 02109–3912; 617/918–1413.
- James Desir, Region 2 (NJ, NY, PR, VI), U.S. EPA, 290 Broadway, New York, NY 10007–1866; 212/637–4342.
- Lorie Baker (ASRC), Region 3 (DE, DC, MD, PA, VA, WV), U.S. EPA, Library, 1650 Arch Street, Mailcode 3HS12, Philadelphia, PA 19103; 215/814–3355.
- Cathy Amoroso, Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street, SW, Mailcode 9T25, Atlanta, GA 30303; 404/562–8637.
- Todd Quesada, Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Librarian/SFD Records Manager SRC–7J, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604; 312/886–4465.
- Brenda Cook, Region 6 (AR, LA, NM, OK, TX), U.S. EPA, 1445 Ross Avenue, Suite 1200, Mailcode 6SFTS, Dallas, TX 75202–2733; 214/665–7436.
- Kumud Pyakuryal, Region 7 (IA, KS, MO, NE), U.S. EPA, 11201 Renner Blvd., Mailcode SUPRSTAR, Lenexa, KS 66219; 913/551–7956.
- Victor Ketellapper, Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 1595 Wynkoop Street, Mailcode 8EPR–B, Denver, CO 80202–1129; 303/312–6578.
- Eugenia Chow, Region 9 (AZ, CA, HI, NV, AS, GU, MP), U.S. EPA, 75 Hawthorne Street, Mailcode SFD 6–1, San Francisco, CA 94105; 415/972–3160.
- Ken Marcy, Region 10 (AK, ID, OR, WA), U.S. EPA, 1200 6th Avenue, Mailcode ECL–112, Seattle, WA 98101; 206/463–1349.

You may also request copies from the EPA Headquarters or the regional dockets. An informal request, rather than a formal written request under the Freedom of Information Act, should be the ordinary procedure for obtaining copies of any of these documents. Please note that due to the difficulty of reproducing oversized maps, oversized maps may be viewed only in-person; since the EPA dockets are not equipped to both copy and mail out such maps or scan them and send them out electronically.

You may use the docket at *https://www.regulations.gov* to access documents in the Headquarters docket. Please note that there are differences between the Headquarters docket and the regional dockets and those differences are outlined in this preamble below.

C. What documents are available for public review at the EPA Headquarters docket?

The Headquarters docket for this proposed rule contains the following for the sites proposed in this rule: HRS score sheets; documentation records describing the information used to compute the score; information for any sites affected by particular statutory requirements or the EPA listing policies; and a list of documents referenced in the documentation record.

D. What documents are available for public review at the EPA regional dockets?

The regional dockets for this proposed rule contain all of the information in the Headquarters docket plus the actual reference documents containing the data principally relied upon and cited by the EPA in calculating or evaluating the HRS score for the sites. These reference documents are available only in the regional dockets.

E. How do I submit my comments?

Follow the online instructions detailed above in the **ADDRESSES** section for submitting comments. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

F. What happens to my comments?

The EPA considers all comments received during the comment period. Significant comments are typically addressed in a support document that the EPA will publish concurrently with the **Federal Register** document if, and when, the site is listed on the NPL.

G. What should I consider when preparing my comments?

Comments that include complex or voluminous reports, or materials prepared for purposes other than HRS scoring, should point out the specific information that the EPA should consider and how it affects individual HRS factor values or other listing criteria (*Northside Sanitary Landfill* v. *Thomas,* 849 F.2d 1516 (D.C. Cir. 1988)). The EPA will not address voluminous comments that are not referenced to the HRS or other listing criteria. The EPA will not address comments unless they indicate which component of the HRS documentation record or what particular point in the EPA's stated eligibility criteria is at issue.

H. May I submit comments after the public comment period is over?

Generally, the EPA will not respond to late comments. The EPA can guarantee only that it will consider those comments postmarked by the close of the formal comment period. The EPA has a policy of generally not delaying a final listing decision solely to accommodate consideration of late comments.

I. May I view public comments submitted by others?

During the comment period, comments are placed in the Headquarters docket and are available to the public on an ''as received'' basis. A complete set of comments will be available for viewing in the regional dockets approximately one week after the formal comment period closes.

All public comments, whether submitted electronically or in paper form, will be made available for public viewing in the electronic public docket at *https://www.regulations.gov* as the EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI) or other information whose disclosure is restricted by statute. Once in the public dockets system, select ''search,'' then key in the appropriate docket ID number.

J. May I submit comments regarding sites not currently proposed to the NPL?

In certain instances, interested parties have written to the EPA concerning sites that were not at that time proposed to the NPL. If those sites are later proposed to the NPL, parties should review their earlier concerns and, if still appropriate, resubmit those concerns for consideration during the formal comment period. Site-specific

correspondence received prior to the period of formal proposal and comment will not generally be included in the docket.

II. Background

A. What are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA'' or ''the Act''), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act (''SARA''), Public Law 99–499, 100 Stat. 1613 *et seq.*

B. What is the NCP?

To implement CERCLA, the EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan (''NCP''), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances or releases or substantial threats of releases into the environment of any pollutant or contaminant that may present an imminent or substantial danger to the public health or welfare. The EPA has revised the NCP on several occasions. The most recent comprehensive revision was on March 8, 1990 (55 FR 8666).

As required under section 105(a)(8)(A) of CERCLA, the NCP also includes ''criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable taking into account the potential urgency of such action, for the purpose of taking removal action.'' ''Removal'' actions are defined broadly and include a wide range of actions taken to study, clean up, prevent or otherwise address releases and threatened releases of hazardous substances, pollutants or contaminants (42 U.S.C. 9601(23)).

C. What is the National Priorities List (NPL)?

The NPL is a list of national priorities among the known or threatened releases of hazardous substances, pollutants or contaminants throughout the United States. The list, which is appendix B of the NCP (40 CFR part 300), was required under section 105(a)(8)(B) of CERCLA, as amended. Section 105(a)(8)(B) defines the NPL as a list of ''releases'' and the highest priority ''facilities'' and requires that the NPL be revised at least annually. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is only of limited significance, however, as it does not assign liability to any party or to the owner of any specific property. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

For purposes of listing, the NPL includes two sections, one of sites that are generally evaluated and cleaned up by the EPA (the ''General Superfund section''), and one of sites that are owned or operated by other federal agencies (the ''Federal Facilities section''). With respect to sites in the Federal Facilities section, these sites are generally being addressed by other federal agencies. Under Executive Order 12580 (52 FR 2923, January 29, 1987) and CERCLA section 120, each federal agency is responsible for carrying out most response actions at facilities under its own jurisdiction, custody or control, although the EPA is responsible for preparing a Hazard Ranking System (''HRS'') score and determining whether the facility is placed on the NPL.

D. How are sites listed on the NPL?

There are three mechanisms for placing sites on the NPL for possible remedial action (see 40 CFR 300.425(c) of the NCP): (1) A site may be included on the NPL if it scores sufficiently high on the HRS, which the EPA promulgated as appendix A of the NCP (40 CFR part 300). The HRS serves as a screening tool to evaluate the relative potential of uncontrolled hazardous substances, pollutants or contaminants to pose a threat to human health or the environment. On December 14, 1990 (55 FR 51532), the EPA promulgated revisions to the HRS partly in response to CERCLA section 105(c), added by SARA. On January 9, 2017 (82 FR 2760), a subsurface intrusion component was added to the HRS to enable the EPA to consider human exposure to hazardous substances or pollutants and contaminants that enter regularly occupied structures through subsurface intrusion when evaluating sites for the NPL. The current HRS evaluates four pathways: Ground water, surface water, soil exposure and subsurface intrusion, and air. As a matter of agency policy, those sites that score 28.50 or greater on the HRS are eligible for the NPL. (2) Pursuant to 42 U.S.C. 9605(a)(8)(B), each state may designate a single site as its top priority to be listed on the NPL, without any HRS score. This provision of CERCLA requires that, to the extent practicable, the NPL include one facility designated by each state as the greatest danger to public health, welfare or the environment among known facilities in the state. This mechanism for listing is set out in the NCP at 40 CFR 300.425(c)(2). (3) The third mechanism for listing, included in the NCP at 40 CFR 300.425(c)(3), allows certain sites to be listed without any HRS score, if all of the following conditions are met:

- The Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service has issued a health advisory that recommends dissociation of individuals from the release.
- The EPA determines that the release poses a significant threat to public health.
- The EPA anticipates that it will be more cost-effective to use its remedial authority than to use its removal authority to respond to the release.

The EPA promulgated an original NPL of 406 sites on September 8, 1983 (48 FR 40658) and generally has updated it at least annually.

E. What happens to sites on the NPL?

A site may undergo remedial action financed by the Trust Fund established under CERCLA (commonly referred to as the ''Superfund'') only after it is placed on the NPL, as provided in the NCP at 40 CFR 300.425(b)(1). (''Remedial actions'' are those ''consistent with permanent remedy, taken instead of or in addition to removal actions. * * *'' 42 U.S.C. 9601(24).) However, under 40 CFR 300.425(b)(2) placing a site on the NPL ''does not imply that monies will be expended.'' The EPA may pursue other appropriate authorities to respond to the releases, including enforcement action under CERCLA and other laws.

F. Does the NPL define the boundaries of sites?

The NPL does not describe releases in precise geographical terms; it would be neither feasible nor consistent with the limited purpose of the NPL (to identify releases that are priorities for further evaluation), for it to do so. Indeed, the precise nature and extent of the site are typically not known at the time of listing.

Although a CERCLA ''facility'' is broadly defined to include any area

where a hazardous substance has ''come to be located'' (CERCLA section 101(9)), the listing process itself is not intended to define or reflect the boundaries of such facilities or releases. Of course, HRS data (if the HRS is used to list a site) upon which the NPL placement was based will, to some extent, describe the release(s) at issue. That is, the NPL site would include all releases evaluated as part of that HRS analysis.

When a site is listed, the approach generally used to describe the relevant release(s) is to delineate a geographical area (usually the area within an installation or plant boundaries) and identify the site by reference to that area. However, the NPL site is not necessarily coextensive with the boundaries of the installation or plant, and the boundaries of the installation or plant are not necessarily the ''boundaries'' of the site. Rather, the site consists of all contaminated areas within the area used to identify the site, as well as any other location where that contamination has come to be located, or from where that contamination came.

In other words, while geographic terms are often used to designate the site (*e.g.,* the ''Jones Co. Plant site'') in terms of the property owned by a particular party, the site, properly understood, is not limited to that property (*e.g.,* it may extend beyond the property due to contaminant migration), and conversely may not occupy the full extent of the property (*e.g.,* where there are uncontaminated parts of the identified property, they may not be, strictly speaking, part of the ''site''). The ''site'' is thus neither equal to, nor confined by, the boundaries of any specific property that may give the site its name, and the name itself should not be read to imply that this site is coextensive with the entire area within the property boundary of the installation or plant. In addition, the site name is merely used to help identify the geographic location of the contamination, and is not meant to constitute any determination of liability at a site. For example, the name ''Jones Co. Plant site,'' does not imply that the Jones Company is responsible for the contamination located on the plant site.

The EPA regulations provide that the remedial investigation (''RI'') ''is a process undertaken . . . to determine the nature and extent of the problem presented by the release'' as more information is developed on site contamination, and which is generally performed in an interactive fashion with the feasibility Study (''FS'') (40 CFR 300.5). During the RI/FS process, the release may be found to be larger or smaller than was originally thought, as more is learned about the source(s) and the migration of the contamination. However, the HRS inquiry focuses on an evaluation of the threat posed and therefore the boundaries of the release need not be exactly defined. Moreover, it generally is impossible to discover the full extent of where the contamination ''has come to be located'' before all necessary studies and remedial work are completed at a site. Indeed, the known boundaries of the contamination can be expected to change over time. Thus, in most cases, it may be impossible to describe the boundaries of a release with absolute certainty. Further, as noted previously, NPL listing does not assign liability to any party or to the owner of any specific property. Thus, if a party does not believe it is liable for releases on discrete parcels of property, it can submit supporting information to the agency at any time after it receives notice it is a potentially responsible party.

For these reasons, the NPL need not be amended as further research reveals more information about the location of the contamination or release.

G. How are sites removed from the NPL?

The EPA may delete sites from the NPL where no further response is appropriate under Superfund, as explained in the NCP at 40 CFR 300.425(e). This section also provides that the EPA shall consult with states on proposed deletions and shall consider whether any of the following criteria have been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required;

(ii) All appropriate Superfund-financed response has been implemented and no further response action is required; or

(iii) The remedial investigation has shown the release poses no significant threat to public health or the environment, and taking of remedial measures is not appropriate.

H. May the EPA delete portions of sites from the NPL as they are cleaned up?

In November 1995, the EPA initiated a policy to delete portions of NPL sites where cleanup is complete (60 FR 55465, November 1, 1995). Total site cleanup may take many years, while portions of the site may have been cleaned up and made available for productive use.

I. What is the construction completion list (CCL)?

The EPA also has developed an NPL construction completion list (''CCL'') to simplify its system of categorizing sites and to better communicate the successful completion of cleanup activities (58 FR 12142, March 2, 1993). Inclusion of a site on the CCL has no legal significance.

Sites qualify for the CCL when: (1) Any necessary physical construction is complete, whether or not final cleanup levels or other requirements have been achieved; (2) the EPA has determined that the response action should be limited to measures that do not involve construction (*e.g.,* institutional controls); or (3) the site qualifies for deletion from the NPL. For more information on the CCL, see the EPA's internet site at *https://www.epa.gov/superfund/construction-completions-national-priorities-list-npl-sites-number*.

J. What is the Sitewide Ready for Anticipated Use measure?

The Sitewide Ready for Anticipated Use measure (formerly called Sitewide Ready-for-Reuse) represents important Superfund accomplishments and the measure reflects the high priority the EPA places on considering anticipated future land use as part of the remedy selection process. See Guidance for Implementing the Sitewide Ready-for-Reuse Measure, May 24, 2006, OSWER 9365.0–36. This measure applies to final and deleted sites where construction is complete, all cleanup goals have been achieved, and all institutional or other controls are in place. The EPA has been successful on many occasions in carrying out remedial actions that ensure protectiveness of human health and the environment for current and future land uses, in a manner that allows contaminated properties to be restored to environmental and economic vitality. For further information, please go to *https://www.epa.gov/superfund/about-superfund-cleanup-process#tab-9*.

K. What is state/tribal correspondence concerning NPL listing?

In order to maintain close coordination with states and tribes in the NPL listing decision process, the EPA's policy is to determine the position of the states and tribes regarding sites that the EPA is considering for listing. This consultation process is outlined in two memoranda that can be found at the following website: *https://www.epa.gov/superfund/statetribal-correspondence-concerning-npl-site-listing*.

The EPA has improved the transparency of the process by which state and tribal input is solicited. The EPA is using the Web and where appropriate more structured state and tribal correspondence that (1) explains the concerns at the site and the EPA's

rationale for proceeding; (2) requests an explanation of how the state intends to address the site if placement on the NPL is not favored; and (3) emphasizes the transparent nature of the process by informing states that information on their responses will be publicly available.

A model letter and correspondence from this point forward between the EPA and states and tribes where applicable, is available on the EPA's website at *https://www.epa.gov/superfund/statetribal-correspondence-concerning-npl-site-listing.*

III. Contents of This Proposed Rule

A. Proposed Additions to the NPL

In this proposed rule, the EPA is proposing to add five sites to the NPL, all to the General Superfund section. All of the sites in this rule are being proposed for NPL addition based on an HRS score of 28.50 or above.

The sites are presented in the table below.

General Superfund section:

State	Site name	City/county
DE	Blades Groundwater	Blades.
KS	Caney Residential Yards	Caney.
MN	Highway 100 and County Road 3 Groundwater Plume	St. Louis Park and Edina.
OK	Henryetta Iron and Metal	Henryetta.
SC	Clearwater Finishing	Clearwater.

IV. Statutory and Executive Order Reviews

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

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

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

B. Executive Order 13771: Reducing 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 (PRA)

This action does not impose an information collection burden under the PRA. This rule does not contain any information collection requirements that require approval of the OMB.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This rule listing sites on the NPL does not impose any obligations on any group, including small entities. This rule also does not establish standards or requirements that any small entity must meet and imposes no direct costs on any small entity. Whether an entity, small or otherwise, is liable for response costs for a release of hazardous substances depends on whether that entity is liable under CERCLA 107(a). Any such liability exists regardless of whether the site is listed on the NPL through this rulemaking.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments or the private sector. Listing a site on the NPL does not itself impose any costs. Listing does not mean that the EPA necessarily will undertake remedial action. Nor does listing require any action by a private party, state, local or tribal governments or determine liability for response costs. Costs that arise out of site responses result from future site-specific decisions regarding what actions to take, not directly from the act of placing a site on the NPL.

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. Listing a site on the NPL does not impose any costs on a tribe or require a tribe to take remedial action. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because this action itself is procedural in nature (adds sites to a list) and does not, in and of itself, provide protection from environmental health and safety risks. Separate future regulatory actions are required for mitigation of environmental health and safety risks.

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

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

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations because it does not affect the level of protection provided to human health or the environment. As discussed in Section I.C. of the preamble to this action, the NPL is a list

of national priorities. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with a release of hazardous substances, pollutants or contaminants. The NPL is of only limited significance as it does not assign liability to any party. Also, placing a site on the NPL does not mean that any remedial or removal action necessarily need be taken.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: October 28, 2019.

Peter C. Wright,

Assistant Administrator, Office of Land and Emergency Management.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 300 as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p.193.

■ 2. Table 1 of appendix B to part 300 is amended by adding the entries for ''DE, Blades Groundwater, Blades'', ''KS, Caney Residential Yards, Caney'', ''MN, Highway 100 and County Road 3 Groundwater Plume, St. Louis Park and Edina'', ''OK, Henryetta Iron and Metal, Henryetta'', and ''SC, Clearwater Finishing, Clearwater'' in alphabetical order by state and site name to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes (a)
*	* * *	* * *	*
DE	Blades Groundwater	Blades.	
*	* * *	* * *	*
KS	Caney Residential Yards	Caney.	
*	* * *	* * *	*
MN	Highway 100 and County Road 3 Groundwater Plume.	St. Louis Park and Edina.	
*	* * *	* * *	*
OK	Henryetta Iron and Metal	Henryetta.	
*	* * *	* * *	*
SC	Clearwater Finishing	Clearwater.	
*	* * *	* * *	*

(a) A = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

* * * * *

[FR Doc. 2019–24154 Filed 11–6–19; 4:15 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA–HQ–OPPT–2018–0320; FRL–10001–44]

RIN 2070–AK21

Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Revisions to the CBI Substantiation Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: In response to a recent federal circuit court decision, EPA is proposing revisions to existing and proposed substantiation requirements for certain confidential business information (CBI) claims made under the Toxic Substances Control Act (TSCA). Specifically, EPA is proposing two additional questions that manufacturers and processors would be required to answer to substantiate certain CBI claims for specific chemical identities; and is proposing procedures for manufacturers and processors to use in amending certain previously-submitted substantiations to include responses to the additional questions. These proposed revisions supplement the proposed rule issued in the **Federal Register** of April 23, 2019, and would amend the TSCA Inventory Notification (Active-Inactive) Requirements rule promulgated in the **Federal Register** of August 11, 2017.

DATES: Comments must be received on or before December 9, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0320, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket,

along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Scott M. Sherlock, Environmental Assistance Division (Mail code 7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8257; email address: *sherlock.scott@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you reported a confidential chemical substance under the TSCA Inventory Notification (Active-Inactive) Requirements rule (hereinafter ''Active-Inactive Rule'') (Ref. 1) (40 CFR part 710, subpart B) through a Notice of Activity (NOA) Form A (Ref. 2) or NOA Form B (Ref. 3) and sought to maintain an existing CBI claim for a specific chemical identity. You may also be affected by this action if you anticipate reporting a confidential chemical substance under the Active-Inactive Rule through an NOA Form B in the future, and anticipate seeking to maintain an existing CBI claim for a specific chemical identity at that time. The following North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

- Chemical manufacturing or processing (NAICS code 325).
- Petroleum and Coal Products Manufacturing (NAICS code 324).

''Manufacture'' is defined by TSCA section 3(9) (15 U.S.C. 2602(9)) and 40 CFR 710.3(d) to include ''import.'' Accordingly, all references to manufacturers in this document should be understood to include importers.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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

EPA is proposing this rule pursuant to the authority in TSCA section 8(b), 15 U.S.C. 2607(b). See also Units I.B and II.B in EPA's proposed rule entitled ''Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory,'' issued in the **Federal Register** of April 23, 2019 (hereinafter ''2019 Proposed Rule'') (Ref. 4), which proposed provisions to be codified in 40 CFR 710, subpart C.

C. What action is the Agency taking?

EPA is supplementing the 2019 Proposed Rule (Ref. 4), which proposed to use the same CBI substantiation questions that were promulgated in the Active-Inactive Rule (Ref. 1) and codified in 40 CFR 710, subpart B. EPA is now proposing to revise the substantiation questions promulgated in the Active-Inactive Rule. See the discussions in Unit II.

As discussed in more detail in Unit III., this supplemental proposed rule presents two additional questions that EPA is proposing manufacturers and processors would be required to answer to substantiate CBI claims for specific chemical identities asserted in an NOA Form A or B. To ensure that EPA receives sufficient information to review and approve or deny all specific chemical identity CBI claims asserted in an NOA Form A or B, EPA is also proposing procedures for manufacturers and processors to use in supplementing previously-submitted substantiations to include responses to the additional questions.

D. Why is the Agency taking this action?

In response to the federal circuit court decision that is discussed in more detail in Unit II.C., EPA is reconsidering the inclusion of substantiation questions directly related to a chemical identity's susceptibility to reverse engineering. Because the 2019 Proposed Rule specifically references the substantiation questions promulgated in the Active-Inactive Rule that were subsequently subject to the federal court decision, EPA believes it is most efficient and straightforward to address the substantiation questions for both rules in this supplemental proposed rule. This will allow stakeholders to submit a single set of comments pertaining to EPA's inclusion of substantiation questions regarding reverse engineering in light of the federal court's decision and supports EPA's efforts to maintain consistency in the manner by which these two closely related rules address the issue. EPA intends to consider comments received and finalize amendments to the existing substantiation questions in 40 CFR 710, subpart B as part of the final rule promulgating 40 CFR 710, subpart C.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of adding two additional questions related to substantiation of CBI claims for specific chemical identity to the 2019 Proposed Rule and the previous Active-Inactive Rule. A memorandum outlining the estimated costs, entitled ''Burden and Cost Estimates for the Supplemental Notice of Proposed Rulemaking: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory'' (Ref. 5), has been prepared for this supplemental proposed rule, is available in the docket, and is briefly summarized here. The incremental change to requirements involves the reporting activity of addressing two additional CBI substantiation questions, which is an activity similar to those already included in the Active-Inactive Rule and in the 2019 Proposed Rule.

1. *Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (proposed subpart C of 40 CFR part 710, as proposed to be amended by this supplemental proposed rule).* As explained in Unit I.E of the 2019 Proposed Rule, companies potentially affected by the 2019 Proposed Rule fall into three groups of reporters who made a CBI claim for a specific chemical identity in their NOA Form A. Group (1) consists of those reporters who already voluntarily submitted substantiation as part of the NOA Form A submission process and who will now need to supplement their substantiations. Group (2) consists of those reporters who would be eligible to reference some other previous substantiation made to EPA within the last five years, exempting them from the requirement to submit new substantiation. Group (3) consists of those reporters who would be required to submit a full substantiation as they did not previously substantiate the claim, either as part of the NOA Form A voluntary substantiation process, or as part of some other submission within the last five years. Under this supplemental proposed rule, Groups (1) and (3) would be required to submit responses to the two proposed additional substantiation questions. There would be no additional requirements for Group (2).

2. *Active-Inactive Rule (subpart B of 40 CFR part 710, as proposed to be amended by this supplemental proposed rule).* Under the requirements of the Active-Inactive Rule, as proposed to be amended by this supplemental proposed rule, all reporters who assert a CBI claim for specific chemical

identity in their NOA Form B would be required to address the two proposed additional substantiation questions. As detailed in the Active-Inactive rule at 40 CFR 710.25(c) and 710.27, reporters submitting an NOA Form B are those who intend to manufacture or process for nonexempt purposes a chemical substance designated as inactive on the TSCA Inventory. Note that Form B reporting is ongoing, compared to the one-time reporting associated with Form A.

3. *Total estimated incremental impacts.* Table 1 summarizes the incremental impacts of the supplemental proposed rule for each group according to Form/rule/ICR. The incremental increase in unit burden for the two additional substantiation questions is estimated at 0.19 hours per affected chemical-specific submission. Total incremental burden for one-time reporting on NOA Form A is 1,123 hours with associated cost of approximately $87,000 per year; total incremental burden for reporting on NOA Form B is 0.4 hours per year with associated cost at about $29 per year.

TABLE 1—INCREMENTAL IMPACTS OF SUPPLEMENTAL PROPOSED RULE

Rule/form	Frequency	Respondents	Responses (chemical-specific submissions)	Burden (hours)	Cost (2018$)
Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory					
Form A Group (1)—Submissions Supplementing Voluntary Upfront CBI Substantiation.	One-time	149	3,137	595	$46,090
Form A Group (2)—Submissions with CBI Substantiation Using Reference.	One-time	23	98	0	0
Form A Group (3)—Submissions with Full CBI Substantiation.	One-time	103	2,751	528	40,964
Total, Form A	.....	275	.....	1,123	87,054
Active-Inactive Rule					
Form B—Submissions with Full CBI Substantiation	Annual	1	2	0.4	29

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

1. Submitting CBI. Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a CD–ROM or other electronic media that you mail to EPA, mark the outside of the media as CBI and then identify electronically within the media the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

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

II. Background

A. What is the Active-Inactive Rule?

TSCA section 8(b) requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either ''active'' or ''inactive'' in U.S. commerce. To accomplish that, the 2017 Active-Inactive Rule (Ref. 1), codified in 40 CFR part 710, subpart B, established a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for nonexempt commercial purposes during the 10-year time period ending on June 21, 2016, with provision to also allow notification by processors. EPA used these notifications—filed on an NOA Form A—to distinguish active substances from inactive substances, and now includes the active and inactive designations on the TSCA Inventory. The Active-Inactive Rule also established procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for nonexempt commercial purposes is expected to resume. On receiving forward-looking notification, which is filed on an NOA Form B, EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. The one-time submission period for NOA Form A ended on October 5, 2018, while the NOA Form B will be submitted on an ongoing basis.

Consistent with TSCA sections 8(b)(4)(B)(ii) and (5)(B)(ii), the Active-Inactive Rule provided that manufacturers and processors filing an NOA Form A or B could seek to maintain an existing claim for protection against disclosure of the specific chemical identity of a chemical substance as confidential by including such a request on their NOA Form A or B. Through this process established in 40 CFR 710.37(a), manufacturers and processors secured an opportunity to maintain the CBI status of a specific chemical identity on the confidential portion of the TSCA Inventory. The Active-Inactive Rule required NOA Form B submitters to substantiate these CBI claims not later than 30 days after submitting their NOA Form B by answering substantiation questions set forth in the Rule and codified at 40 CFR 710.37(c). The Rule also permitted NOA Form A submitters to voluntarily substantiate their CBI claims for specific chemical identities at the time of filing their NOA Form A by answering the same substantiation questions. The Active-Inactive Rule did not require NOA Form A submitters to substantiate these CBI claims because TSCA section 8(b)(4)(C) directed EPA to promulgate another rule addressing the substantiation and review of those claims.

B. What is the 2019 Proposed Rule?

On April 23, 2019, EPA proposed to establish a plan to review all CBI claims for specific chemical identities asserted in an NOA Form A, including the procedures for substantiating and

reviewing those claims (Ref. 4). The 2019 Proposed Rule was presented as a follow-on rulemaking to the 2017 Active-Inactive Rule. See detailed background in Unit II. of the 2019 Proposed Rule (Ref. 4). As such, it specifically referenced the substantiation questions for specific chemical identity CBI claims that had been promulgated in the Active-Inactive Rule and codified at 40 CFR 710.37(c), *i.e.,* proposing to require manufacturers and processors who had submitted an NOA Form A requesting to maintain an existing CBI claim for a specific chemical identity to substantiate that CBI claim by submitting answers to the substantiation questions in 40 CFR 710.37(c). Manufacturers and processors who had already submitted answers to those substantiation questions pursuant to the voluntary process established in the Active-Inactive Rule would have been exempt from any further substantiation requirements under the 2019 Proposed Rule. Manufacturers and processors who had provided substantiations for specific chemical identity CBI claims in another submission made to EPA less than five years before the substantiation deadline that would be set in the final rule, would also have been exempt from further substantiation requirements under the 2019 Proposed Rule, provided that they reported to EPA certain identifying information about the previously submitted substantiation (submission date; submission type; and case number, transaction ID, or equivalent identifier that would uniquely identify the previous submission that contained the substantiation).

C. What is the Federal Circuit Court decision?

On April 26, 2019, the U.S. Court of Appeals for the District of Columbia Circuit entered a judgment in *Environmental Defense Fund* v. *EPA,* 922 F.3d 446 (D.C. Cir. 2019), granting in part and denying in part a petition for review of the Active-Inactive Rule. The court ordered a limited remand of the Active-Inactive Rule, without vacatur, for EPA ''to address its arbitrary elimination of substantiation questions regarding reverse engineering.'' 922 F.3d at 459. Citing the statutory requirements at TSCA section 14(c)(1)(B)(iv) and (c)(3) that a person asserting a CBI claim must include a statement that the person has ''a reasonable basis to believe that the information is not readily discoverable through reverse engineering,'' and must ''substantiate the claim,'' the court found that EPA's ''omission of any inquiry into a chemical identity's susceptibility to reverse engineering effectively excised a statutorily required criterion from the substantiation process.'' *Id.* at 454. Because the Active-Inactive Rule did not explain the gap in substantiation or acknowledge the consequence of the omission, the court found the Active-Inactive Rule to be arbitrary and capricious to the extent that it omitted any substantiation requirement pertaining to reverse engineering. *Id.* The court remanded the Active-Inactive Rule to EPA without vacatur, leaving all provisions of the Active-Inactive Rule in effect while EPA conducts further proceedings on remand. A copy of the court's opinion is available in the docket for this action.

III. Summary of Proposed Revisions

In response to the court's remand and discussed in detail in this unit, EPA is proposing to amend 40 CFR 710.37(c) to include two additional substantiation questions related to a specific chemical identity's susceptibility to reverse engineering. These substantiation questions would apply to manufacturers and processors who request(ed) to maintain a CBI claim for a specific chemical identity in either an NOA Form A or an NOA Form B. EPA is also proposing to require any manufacturer or processor who has already submitted answers to the substantiation questions currently listed in the Active-Inactive Rule at 40 CFR 710.37(c) to supplement their submission by adding answers to the newly proposed questions relating to reverse engineering. Finally, EPA is proposing to revise the proposed substantiation exemption for NOA Form A submitters who have previously submitted a substantiation outside of the Active-Inactive Rule process, to clarify that this proposed exemption would apply only where the previously submitted substantiation is responsive to all substantiation questions in 40 CFR 710.37(c) as amended by the final rule to the 2019 Proposed Rule.

A. What additional substantiation questions is EPA proposing?

To solicit additional information about a specific chemical identity's susceptibility to reverse engineering, EPA is proposing to add the following two questions to 40 CFR 710.37(c)(2):

1. Does this particular chemical substance leave the site of manufacture or processing in any form, *e.g.,* as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

2. If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

These two questions are intended to assist EPA in gathering the information it uses to evaluate confidentiality claims. They are modeled after substantiation questions that appear in EPA's existing regulations governing CBI claims for specific chemical identities that are asserted in Notices of Commencement (NOCs) (40 CFR 720.85(b)(3)(iv)(H)–(I)) and Chemical Data Reporting (CDR) submissions (40 CFR 711.30(b)(1)(viii)–(ix)). EPA proposed nearly identical questions in the January 13, 2017 Active-Inactive proposed rule (Ref. 9) and in the April 25, 2019 CDR revisions proposed rule (Ref. 10). The first question has been modified from the version that appeared in the earlier proposed and existing rules to add ''or processing,'' to the first sentence, in recognition of the fact that unlike NOCs and CDR submissions, which are only filed by manufacturers, NOA forms may be filed (and hence CBI claims may be asserted and substantiated) by both manufacturers and processors. The second question is unchanged from the version that appeared in the Active-Inactive proposed rule and in the existing and proposed CDR rules. (Both questions are phrased slightly differently in the NOC regulation than in the other existing and proposed regulations.)

As indicated previously, EPA's 2019 Proposed Rule, ''Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory,'' cross-referenced the substantiation questions for chemical identity CBI claims at 40 CFR 710.37(c). Under this supplemental proposed rule that cross-reference would remain unchanged, because it would include the two additional substantiation questions that EPA proposes to add to 40 CFR 710.37(c).

The proposed substantiation questions are intended to solicit information that is known to or reasonably ascertainable by the respondent (the manufacturer or processor making the CBI claim). ''Known to or reasonably ascertainable by'' is defined in 40 CFR 710.23 to mean ''all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.'' EPA intends that the inquiry into whether a chemical substance can be identified by analysis of the product would be answered based on information that is known to or reasonably ascertainable by the respondent, about reasonably available analytical capabilities currently in use

by the chemical industry. EPA does not intend to require respondents to initiate a special research program to answer the inquiry, or to speculate about hypothetical analytical capabilities.

B. Who would have to answer these substantiation questions?

The additional substantiation questions in this supplemental proposed rule would apply to manufacturers and processors who requested to maintain a CBI claim for a specific chemical identity in either of two commercial activity notices submitted to EPA pursuant to the Active-Inactive Rule (40 CFR part 710, subpart B): An NOA Form A (retrospective commercial activity reporting) or an NOA Form B (forward-looking commercial activity reporting). The additional substantiation questions would also apply to manufacturers and processors who submit an NOA Form B in the future that requests to maintain a CBI claim for a specific chemical identity.

C. When would the additional substantiation be required?

Manufacturers and processors who have not yet submitted any substantiation to EPA would be required to submit answers to the two newly proposed substantiation questions at the same time as they submit the rest of their required substantiation. The substantiation deadline for those entities would depend on whether the chemical identity CBI claim was asserted in an NOA Form A or B. For persons substantiating a chemical identity CBI claim asserted in an NOA Form A, if finalized as proposed, EPA's 2019 Proposed Rule would require that all substantiations be filed not later than 90 days after the effective date of the final rule. EPA is not altering or otherwise revisiting that proposed requirement in this supplemental proposed rule. For persons substantiating a chemical identity CBI claim asserted in an NOA Form B, the Active-Inactive Rule requires that all substantiations be submitted within 30 days of submitting the NOA Form B. See 40 CFR 710.37(a)(2). That provision is currently in effect, and EPA is not proposing to amend or otherwise revisit that requirement in this supplemental proposed rule.

Manufacturers and processors who have already voluntarily submitted substantiation to EPA with an NOA Form A, or who will have submitted substantiation for a chemical identity CBI claim asserted in an NOA Form B before the revisions to 40 CFR 710.37(c) are finalized and go into effect, would be required to supplement their earlier submission with answers to the two new substantiation questions. For persons substantiating a chemical identity CBI claim asserted in an NOA Form A, EPA is proposing to require submission of the supplemental substantiation by not later than 90 days after the effective date of the final rule, consistent with the other substantiation deadlines in the 2019 Proposed Rule. For persons substantiating a chemical identity CBI claim asserted in an NOA Form B, EPA is proposing to require submission of the supplemental substantiation by not later than 30 days after the effective date of the final rule. The 30-day deadline would facilitate EPA's ability to meet the statutory requirement to ''promptly'' review chemical identity CBI claims asserted in an NOA Form B, see TSCA 8(b)(5)(B)(iii)(II), and would be consistent with the existing 30-day deadline for substantiation of such claims pursuant to 40 CFR 710.37(a)(2).

D. Would this impact the proposed exemption for other previously submitted substantiations?

In the 2019 Proposed Rule, EPA recognized that some persons may have recently substantiated their specific chemical identity CBI claims in other submissions to the Agency outside of the voluntary substantiation process for NOA Form A that was set forth in the Active-Inactive Rule. EPA proposed to exempt those persons from the substantiation requirement in the 2019 Proposed Rule so long as the previous substantiation was submitted less than five years before the substantiation deadline that will be set in the final rule, and the person reports to EPA certain identifying information for the previous substantiation (*i.e.,* submission date and type, and case number, transaction ID, or equivalent identifier).

In this supplemental proposed rule, EPA is also revising the proposed exemption in the 2019 Proposed Rule to clarify that a previously submitted substantiation must contain information that is responsive to all substantiation questions in the final rule to relieve the submitter of the requirement to submit a new substantiation. In other words, to serve as a substitute for a new substantiation, EPA is proposing to require that a previously submitted substantiation must provide information that is substantively equivalent to that sought in the substantiation questions that are ultimately finalized. Substantiations of specific chemical identity CBI claims that were submitted with CDR submissions in accordance with the substantiation procedures at 40 CFR 711.30(b)(1), or with NOCs in accordance with the substantiation procedures at 40 CFR 720.85(b)(3)(iv), would be deemed by EPA as responsive to all substantiation questions in the amended 40 CFR 710.37(c), and could therefore serve as a basis for the proposed exemption. EPA expects that the vast majority of recent substantiations for specific chemical identity CBI claims submitted outside of the voluntary Active-Inactive Rule process would have been submitted pursuant to one of those two regulatory substantiation provisions. Substantiations that were not submitted pursuant to one of those two regulatory provisions (for example, substantiations for CBI claims asserted in submissions under TSCA section 8(e)) may also be responsive to all substantiation questions in the amended 40 CFR 710.37(c), but would need to be evaluated on a case-by-case basis.

E. How would EPA review CBI claims for specific chemical identity?

In the 2019 Proposed Rule, EPA explained that when reviewing CBI claims, EPA would apply the substantive criteria for confidentiality determinations set forth in 40 CFR 2.306(g) and 2.208. See Ref. 4 at 16830. The Active-Inactive Rule likewise incorporated these substantive criteria for confidentiality determinations. See 40 CFR 710.37(a) (referencing the 40 CFR part 2, subpart B procedures for treatment and disclosure of information claimed as confidential). EPA is not proposing to change either the 2019 Proposed Rule or the Active-Inactive Rule (40 CFR 710.37(a)) in this regard. EPA interprets the substantive criteria described in 40 CFR 2.208 and cross-referenced in 40 CFR 2.306(g) to already encompass consideration of a specific chemical identity's susceptibility to reverse engineering.

Specifically, 40 CFR 2.208(c) provides that one of the required criteria for approval of a confidentiality claim is that ''[t]he information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).'' If a specific chemical identity is readily discoverable through reverse engineering, then that chemical identity is reasonably obtainable without the business's consent by other persons by use of legitimate means, and the specific chemical identity would not be entitled to confidential treatment.

EPA notes that on June 24, 2019, the U.S. Supreme Court issued a decision

addressing the test for determining whether commercial information qualifies as ''confidential'' for purposes of Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4). *See Food Marketing Institute* v. *Argus Leader Media,* 139 S. Ct. 2356 (2019). The Court found that, ''[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4.'' 139 S. Ct. at 2366. The Court rejected the ''substantial competitive harm'' test that had long been applied by many courts of appeals, under which certain commercial information could not be deemed ''confidential'' unless disclosure was likely to cause substantial harm to the competitive position of the person from whom the information was obtained. *Id.* at 2361, 2364–66. A copy of the Court's opinion is available in the docket for this action.

Because TSCA section 14(a) incorporates FOIA Exemption 4 as the basic framework for determining whether information is eligible for protection from disclosure under TSCA, the substantive criteria for TSCA confidentiality determinations include the ''substantial competitive harm'' test that courts of appeals had formerly applied under FOIA Exemption 4. See 15 U.S.C. 2613(a), 40 CFR 2.306(g), and 40 CFR 2.208(e)(1). In light of the recent Court decision, EPA is considering whether revisions are warranted to EPA's substantive review criteria for CBI claims not submitted under TSCA. However, EPA is not proposing to remove the ''substantial competitive harm'' review criterion or any related substantiation question for the TSCA CBI claims addressed in this rulemaking, because Congress amended TSCA section 14 in 2016 to specifically require any person asserting a CBI claim under TSCA to include a certified statement that the person has ''a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.'' TSCA section 14(c)(1)(B)(iii), (c)(5); see also TSCA section 14(c)(1)(C)(ii)(II) (referencing substantial competitive harm).

IV. Request for Comments

EPA is seeking public comment on all aspects of this supplemental proposed rule, including the proposed two additional substantiation questions, the proposed revisions to the proposed exemptions from substantiation requirements, the proposed procedures for supplementing previously-submitted substantiations, and whether EPA has appropriately addressed the federal circuit court decision. EPA is seeking comment only on the issues discussed in this supplemental proposed rule and is not reopening comment on any other aspects of the 2019 Proposed Rule or the Active-Inactive Rule. Public comments on the 2019 Proposed Rule that were submitted to the docket by the end of the comment period for that proposed rule (*i.e.,* June 24, 2019) will be considered by EPA and addressed in the final rule.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these references and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Inventory Notification (Active-Inactive) Requirements; Final Rule. **Federal Register**, 82 FR 37520, August. 11, 2017 (FRL–9964–22).
2. EPA. Notice of Activity Form A; Final, 2017.
3. EPA. Notice of Activity Form B; Final, 2017.
4. EPA. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Proposed Rule. **Federal Register**, 84 FR 16826, April 23, 2019 (FRL–9992–05).
5. EPA. Memorandum from Laura Nielsen to Scott Sherlock, *Burden and Cost Estimates for the Supplemental Notice of Proposed Rulemaking: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Docket #EPA–HQ–OPPT–2018–0320),* 2019.
6. EPA. ICR No. 2594.01 *Information Collection Request Proposed Addendum to* TSCA Review Plan CBI Substantiation *Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act.* 2019.
7. EPA. ICR No. 2565.03 *Information Collection Request Proposed Addendum to* TSCA Section 8(b) Reporting Requirements for TSCA *Inventory Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act.* 2019.
8. EPA. Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, 2019.
9. TSCA Inventory Notification (Active-Inactive) Requirements; Proposed Rule. **Federal Register**, 82 FR 4255, January 13, 2017 (FRL–9956–28).
10. TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a); Proposed Rule. **Federal Register**, 84 FR 17692, April 25, 2019 (FRL–9982–16).
11. EPA. *Small Entity Analysis Report for the Final Rule: TSCA Inventory Notification Requirements,* 2017.

VI. Statutory and Executive Order Reviews

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

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

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

This action is expected to be subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017). EPA prepared an analysis of the estimated costs and benefits associated with this action (Ref. 5), which is available in the docket and is summarized in Unit I.E.

C. Paperwork Reduction Act (PRA)

The information collection activities in this supplemental proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* EPA prepared a supplement to the Information Collection Request (ICR) document that was submitted for the 2019 Proposed Rule, which has been assigned EPA ICR No. 2594.02 and OMB Control No. 2070–[New] (Ref. 6). The information collection activities contained in the Active-Inactive Rule are approved by OMB under EPA ICR No. 2565.01 and OMB Control No. 2070–0201 (Ref. 7). You can find a copy of the ICRs in the docket for this rule, and the incremental paperwork burden is briefly summarized here.

The incremental reporting requirements identified in this supplemental proposed rule involve the addition of two substantiation questions that would provide EPA with

information necessary to evaluate confidentiality claims and determine whether the claims qualify for protection from disclosure. Since the incremental burden impacts both ICRs, the summary is presented in Table 2.

TABLE 2—INCREMENTAL PAPERWORK BURDEN ESTIMATES

EPA ICR No.	2565.01	2594.02.
OMB Control No.	2070–0201	2070–[new].
Rulemaking	Active-Inactive Rule	2019 Proposed Rule.
ICR Activities	Ongoing annual burden/cost (forward looking)	One-time burden/cost.
Respondents/affected entities	Persons who manufacture or process chemical substances and submit a Form B with chemical identity substantiation requirements.	Persons who manufacture or process chemical substances and submit a Form A with chemical identity substantiation requirements.
Respondent's obligation to respond	Mandatory	Mandatory.
Frequency of response	On-occasion	Once per chemical.
Estimated total number of respondents	1	275.
Estimated burden per respondents	0.4 hours per year	4 hours.
Estimated total burden	0.4 hours	1,123 hours (one time).
Estimated costs per respondent	$29	$317.
Estimated total costs	$29 per year	$87,054.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations in 40 CFR is consolidated in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this supplemental proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov,* Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than December 9, 2019. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b), 5 U.S.C. 601 *et seq.,* I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities subject to the requirements of this supplemental proposed rule are manufacturers (including importers) and processors of chemical substances. In this supplemental proposed rule, impacts on these small entities are evaluated qualitatively and with respect to the two rules in which small entity impacts are assessed in the small entity analyses (SEAs) prepared for the Active-Inactive Rule (Ref. 11) and for the 2019 Proposed Rule (Ref. 8). The estimated incremental impact on small entities associated with this supplemental proposed rule are presented in the Cost Memo (Ref. 5), which is in the public docket for this action. In that analysis, EPA explains how each component of this supplemental proposed rule does not have a significant economic impact on a substantial number of small entities, and moreover how the combination of the components does not have a significant economic impact on a substantial number of small entities.

In the small entity analysis (SEA) for the NPRM for this proposed rule, EPA found that no small entities from Groups (2) and (3) would experience an impact of greater than 1% of revenues. The same respondents are considered for Groups (2) and (3) for this component of this SNPRM, but at a much lower average incremental cost per respondent. Therefore, the same conclusion from that SEA applies to the corresponding small entities in Groups (2) and (3) potentially affected by this SNPRM.

In the SEA for the Active-Inactive rule, the most burdensome average unit compliance cost selected for assessment was associated with manufacturers (including importers) submitting Form As in the start-up reporting period. The small entities in Group (1) for this SNPRM are drawn from Form A submitters identified in the Active-Inactive rule. Using that reporting group as a basis, EPA found in that SEA that no small entities would experience an impact of greater than 1% of revenues. The Group (1) small entities for this component of the SNPRM represent a subset, and therefore lower number of small entities than evaluated in the most affected group in that SEA. Moreover, EPA reasonably assumes for purposes of this SNPRM SEA that the small entity impacts for this component of this SNPRM associated with Group (1) respondents involve a similar impacts distribution as for the Active-Inactive Form A start-up reporters. Given these considerations and additionally the much lower average incremental cost per respondent in this SNPRM compared to the Active-Inactive rule Form A start-up reporters, the conclusion from the Active-Inactive rule SEA applies to the corresponding small entities in Group (1) potentially affected by this SNPRM.

Similarly, small entities submitting a Form B under the Active-Inactive rule would incur a much lower average incremental cost per respondent than in the Active-Inactive rule's SEA, and therefore the conclusion from the Active-Inactive rule SEA applies to the corresponding small entities potentially affected by this SNPRM.

Considering impacts on small businesses from the components presented in this unit, the information from each component is combined to support the conclusion that the overall impact of this action is minimal and would have no significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action is not expected to impose enforceable duty on any state, local or tribal governments, and the requirements imposed on the private sector are not expected to result in annual expenditures of $100 million or

more for the private sector. As such, EPA has determined that the requirements of UMRA sections 202, 203, 204, or 205 do not apply to this action.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, E.O. 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

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

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

J. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not establish an environmental health or safety standard. This action establishes an information requirement and does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 710

Environmental Protection, Chemicals, Confidential Business Information, Hazardous substances, Reporting and Recordkeeping Requirements.

Dated: October 24, 2019.

Andrew R. Wheeler,

Administrator.

Therefore, it is proposed that 40 CFR chapter I, part 710, subpart B be amended and 40 CFR chapter I, part 710, subpart C, as proposed to be added at 84 FR 16833 (April 23, 2019), be amended as follows:

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

■ 1. The authority citation for part 710 continues to read as follows:

Authority: 15 U.S.C. 2607(a) and (b).

Subpart B—Commercial Activity Notification

■ 2. Amend § 710.37 by adding paragraph (a)(2)(i), and revising paragraph (c)(2) to read as follows:

§ 710.37 Confidentiality claims.

(a) * * *

(2) * * *

(i) Persons who submitted the information described in paragraph (a)(2) of this section before [EFFECTIVE DATE OF THE FINAL RULE] must submit answers to the questions in paragraphs (c)(2)(ii) and (iii) of this section not later than [DATE 30 CALENDAR DAYS AFTER EFFECTIVE DATE OF THE FINAL RULE].

(ii) [Reserved].

* * * * *

(c) * * *

(2) *Substantiation for confidentiality claims for chemical identity.* (i) Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential.

(ii) Does this particular chemical substance leave the site of manufacture or processing in any form, *e.g.,* as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(iii) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

* * * * *

Subpart C—Review Plan

■ 3. Amend § 710.43(b), as proposed to be added at 84 FR 16833 (April 23, 2019), by revising paragraph (b)(1) and paragraph (b)(2) introductory text to read as follows:

§ 710.43 Persons subject to substantiation requirement.

* * * * *

(b) *Exemptions.* (1) Any person who completed the voluntary substantiation process set forth in § 710.37(a)(1) is exempt from the substantiation requirement of this subpart pertaining to the submission of answers to the questions in § 710.37(c)(1) and (2)(i). All remaining requirements of § 710.45 must be met in accordance with the deadline specified in § 710.47(a), including the requirement to submit answers to the questions in 710.37(c)(2)(ii) and (iii), signed and dated by an authorized official, and to complete the certification statement in § 710.37(e).

(2) A person who has previously substantiated the confidentiality claim for a specific chemical identity that the person requested to maintain in a Notice of Activity Form A, by submitting information that is responsive to all questions in § 710.37(c)(1) and (2), is exempt from the substantiation requirement of this subpart if both of the following conditions are met:

* * * * *

■ 4. Revise § 710.47(a), as proposed to be added at 84 FR 16833 (April 23, 2019), to read as follows:

§ 710.47 When to submit substantiation or information on previous substantiation.

(a) All persons required to substantiate a confidentiality claim pursuant to § 710.43(a) or (b)(1) must submit their substantiation not later than [DATE 90 CALENDAR DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

[FR Doc. 2019–23714 Filed 11–7–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2015–0139; 4500090022]

Endangered and Threatened Wildlife and Plants; 12-Month Finding for the California Spotted Owl

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of 12-month finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on petitions to list the California spotted owl (*Strix occidentalis occidentalis*) as an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the California spotted owl. However, we ask the public to submit to us at any time any new information relevant to the status of the subspecies or its habitat.

DATES: The finding in this document was made on November 8, 2019.

ADDRESSES: A detailed description of the basis for this finding is available on the internet at *http://www.regulations.gov* under docket number FWS–R8–ES–2015–0139.

Supporting information used to prepare this finding is available for public inspection, by appointment, during normal business hours, by contacting the person specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any new information, materials, comments, or questions concerning this finding to the person specified under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Josh Hull, telephone: 916–414–6742, email: *josh_hull@fws.gov.* If you use a telecommunications device for the deaf (TDD), please call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding whether or not a petitioned action is warranted within 12 months after receiving any petition for which we have determined contained substantial scientific or commercial information indicating that the petitioned action may be warranted (''12-month finding''). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted but precluded. ''Warranted but precluded'' means that (a) the petitioned action is warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened species, and (b) expeditious progress is being made to add qualified species to the Lists of Endangered and Threatened Wildlife and Plants (Lists) and to remove from the Lists species for which the protections of the Act are no longer necessary. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring that a subsequent finding be made within 12 months of that date. We must publish these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists. The Act defines ''endangered species'' as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and ''threatened species'' as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In considering whether a species may meet the definition of an endangered species or a threatened species because of any of the five factors, we must look beyond the mere exposure of the species to the threat to determine whether the species responds to the threat in a way that causes actual impacts to the species. If there is exposure to a threat, but no response, or only a positive response, that threat does not cause a species to meet the definition of an endangered species or a threatened species. If there is exposure and the species responds negatively, we determine whether that threat drives or contributes to the risk of extinction of the species such that the species warrants listing as an endangered or threatened species. The mere identification of threats that could affect a species negatively is not sufficient to compel a finding that listing is or remains warranted. For a species to be listed or remain listed, we require evidence that these threats are operative threats to the species and its habitat, either singly or in combination, to the point that the species meets the definition of an endangered or a threatened species under the Act.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the California spotted owl (*Strix occidentalis occidentalis*) meets the definition of ''endangered species'' or ''threatened species,'' we considered and thoroughly evaluated the best scientific and commercial information available regarding the past, present, and future threats. We reviewed the petition, information available in our files, and other available published and unpublished information. This evaluation may include information from recognized experts; Federal, State, and tribal governments; academic institutions; foreign governments; private entities; and other members of the public.

The species assessment for the California spotted owl contains more detailed biological information, a thorough analysis of the listing factors, and an explanation of why we determined that this subspecies does not meet the definition of an endangered species or a threatened species. This supporting information can be found on the internet at *http://www.regulations.gov* under docket number FWS–R8–ES–2015–0139. The following is an informational summary of the finding in this document.

Previous Federal Actions

For a detailed history of prior petitions, listing actions, and litigation, please see the 12-month finding published on May 24, 2006 (71 FR 29886). Subsequent to that finding, the Service was petitioned twice to list the California spotted owl as endangered or threatened with critical habitat under the Act. The first petition was submitted in December 2014, by the Wild Nature Institute and John Muir Project of Earth

Island Institute, and the second was submitted in August 2015, by Sierra Forest Legacy and Defenders of Wildlife. On September 18, 2015, the Service published a 90-day finding (80 FR 56423) that the petitions presented substantial scientific or commercial information indicating that listing may be warranted for the California spotted owl. On March 16, 2016, the Center for Biological Diversity challenged the Service's failure to timely issue the 12-month finding in response to the recent petitions (*CBD* v. *Jewell, et al.,* No. 1:16–cv–00503–JDB (D.D.C.)). The parties entered into a settlement agreement whereby the Service committed to submit a 12-month finding on California spotted owl to the **Federal Register** by September 30, 2019. On May 2, 2019, the court extended the deadline until November 4, 2019, due to a previous lapse in appropriations that stopped all progress on the California spotted owl petition finding for a period of time.

Summary of Finding

The California spotted owl is a subspecies of spotted owl that occurs throughout the Sierra Nevada mountain range in California and Nevada; in southern and coastal California in the Coastal, Transverse, and Peninsular mountain ranges; and in Sierra San Pedro Martir in Baja California Norte, Mexico.

In the Sierra Nevada range, a majority of California spotted owls occur within mid-elevation ponderosa pine, mixed-conifer, white fir, and mixed-evergreen forest types, with fewer owls occurring in the lower elevation oak woodlands of the western foothills. On the central coast of California and in southern California, California spotted owls are found in riparian/hardwood forests and woodlands, live oak/big cone fir forests, and redwood/California laurel forests. California spotted owls primarily prey upon a variety of small- to medium-sized mammals, such as northern flying squirrels (*Glaucomys sabrinus*) and woodrats (*Neotoma* spp.). California spotted owls require multi-layered high canopy cover, large trees, coarse woody debris, forest heterogeneity, and nest trees within a patch size large enough to fulfill the needs of the owls and in a particular pattern across the landscape.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the California spotted owl, and we evaluated all relevant considerations under the five listing factors, including any regulatory mechanisms and conservation measures addressing the identified threats. The primary threats affecting the California spotted owl's status include large-scale, high-severity fire; increased tree mortality; drought; effects of climate change; and the invasion of barred owls into the California spotted owl's range. Many of these threats, such as wildfire and increased tree mortality, have been acting on the landscape for several decades, yet over half of the Sierra Nevada portion of the range is in moderate or high condition, meaning that populations in those areas are currently likely to be able to persist through a catastrophic event, and the California spotted owl currently demonstrates high representation and moderate redundancy.

While some threats such as drought, tree mortality, and effects of climate change cannot be addressed by conservation measures, existing conservation measures and regulatory mechanisms will help increase resiliency so that the subspecies can withstand future threats, particularly in the northern Sierra Nevada portion of the owl's range. Specifically, measures described in the 2004 Sierra Nevada Forest Plan Amendment, the 2005 Southern California National Forest Land Management Plans, and other conservation measures will continue to decrease the negative effects of clearcutting and mechanical thinning. They will benefit the California spotted owl by maintaining high canopy cover and large trees within owl territories. Further, increased mechanical thinning will help to reduce the risk of large-scale high-severity fire on the landscape. Though these forest plans and conservation measures cannot fully remove the risk of large-scale high-severity fire, they are reducing the overall potential for wildfires to become the large-scale high-severity fires that are particularly detrimental to California spotted owl habitat. Additionally, the Barred Owl Removal Project is currently reducing the density of barred owls on the landscape. Continued removal of barred owls is expected to stem the expansion of barred owl further into the California spotted owl range.

Though the conditions of California spotted owl habitat and populations are expected to decline in some areas, existing conservation measures and regulatory mechanisms are expected to continue and will reduce the effects of threats to the owl such that the California spotted owl will retain sufficient redundancy, resiliency and representation to allow it to persist into the foreseeable future. Overall, the threats are not affecting the subspecies at such a level to cause it to be in danger of extinction throughout all or a significant portion of its range or to become an endangered species in the foreseeable future throughout all or a significant portion of its range.

Therefore, we find that listing the California spotted owl as an endangered species or threatened species under the Act is not warranted. A detailed discussion of the basis for this finding can be found in the California spotted owl species assessment and other supporting documents (see **ADDRESSES**, above).

New Information

We request that you submit any new information concerning the taxonomy of, biology of, ecology of, status of, or threats to the California spotted owl to the person specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor this subspecies and make appropriate decisions about its conservation and status. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts.

References Cited

The list of the references cited in the petition finding is available on the internet at *http://www.regulations.gov* under docket number FWS–R8–ES–2015–0139 and upon request from the person specified under **FOR FURTHER INFORMATION CONTACT**.

Authors

The primary authors of this document are the staff members of the Species Assessment Team, Ecological Services Program.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 1, 2019.

Margaret E. Everson,

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

[FR Doc. 2019–24336 Filed 11–7–19; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 84, No. 217
Friday, November 8, 2019

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

DEPARTMENT OF AGRICULTURE

Forest Service

Flathead Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Flathead Resource Advisory Committee (RAC) will meet in Kalispell, Montana. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following website: *https://www.fs.usda.gov/main/pts/home*.

DATES: The meeting will be held on Thursday, November 21, 2019, from 4:00 p.m. to 7:00 p.m.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact Meghan Mulholland, RAC Coordinator, by phone at 406–758–5252 or via email at *meghan.mulholland@usda.gov.*

ADDRESSES: The meeting will be held at the Flathead National Forest, Supervisor's Office, 650 Wolfpack Way, Kalispell, Montana.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Flathead National Forest, Supervisor's Office. Please call ahead at 406–758–5200 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Meghan Mulholland, RAC Coordinator, by phone at 406–758–5252 or via email at *meghan.mulholland@usda.gov.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to: Discuss, recommend, and approve the following:

- Total of 14 fee proposals
  - ➢ 1 new fee site
  - ➢ 13 fee increases
- 2 Campgrounds

Lindbergh Lake campground is the only new fee proposal.

- Campgrounds
  - ➢ 1 proposed fee increase to $13 per night
  - ➢ 1 proposed new fee site at $10 per night
- 12 Cabin and lookout rentals

Lookouts and Cabins:

- ➢ 12 proposed fee increases ranging from $50 to $70 per night.

In June 2016, the Secure Rural Schools (SRS) Resource Advisory Committee (RAC) charter enabled SRS RACs to provide recommendations on Forest Service recreation fee proposals; if the designated units are not currently coordinating with another active Recreation RAC; the current charter states that upon request of the Designated Federal Officer (DFO), the SRS RAC may make recommendations regarding:

a. The implementation of a new recreation fee at specific recreation fee site;

b. The implementation of a fee increase at an existing recreation fee;

c. The implementation or elimination of noncommercial, individual special recreation permit fees;

d. The elimination of a recreation fee; and,

e. The expansion or limitation of the recreation fee program.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by Monday, November 18, 2019, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Meghan Mulholland, RAC Coordinator, 650 Wolfpack Way, Kalispell, MT 59901; by email to *meghan.mulholland@usda.gov,* or via facsimile to 406–758–5379.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact Meghan Mulholland, RAC Coordinator, by phone at 406–758–5252 or via email at *meghan.mulholland@usda.gov.* All reasonable accommodation requests are managed on a case by case basis.

Dated: October 31, 2019.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2019–24413 Filed 11–7–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Yavapai Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Yavapai Resource Advisory Committee (RAC) will meet in Prescott, Arizona. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following website: *http://www.fs.usda.gov/main/prescott/workingtogether/advisorycommittees.*

DATES: The meeting will be held on December 11, 2019, from 8:30 a.m. to 12:30 p.m.

All RAC meetings are subject to cancellation. For the status of meeting prior to attendance, please contact Debbie Maneely, RAC Coordinator, by phone at 928–443–8130 or via email at *debbie.maneely@usda.gov.*

ADDRESSES: The meeting will be held at the Prescott Fire Center, 2400 Melville Road, Prescott, Arizona 86301.

Written comments may be submitted as described under *Supplementary Information.* All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Prescott National Forest, Supervisor Office, 344 South Cortez Street, Prescott, Arizona 86303. Please call ahead at 928–443–8000 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Debbie Maneely, RAC Coordinator, Prescott National Forest, 2971 Willow Creek Road, Building 4, Prescott, Arizona 86301, by phone at 928–443–8130 or via email at *debbie.maneely@usda.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Welcome, introduce, and have orientation of RAC members, and

2. Review seven Title II projects, and

3. Rank and select round six Title II projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by November 26, 2019, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Debbie Maneely, RAC Coordinator, Prescott National Forest, 2971 Willow Creek Road, Building 4, Prescott, Arizona 86301, by phone at 928–443–8130 or via email at *debbie.maneely@usda.gov.*

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting Debbie Maneely, RAC Coordinator, by phone at 928–443–8130 or via email at *debbie.maneely@usda.gov.* All reasonable accommodation requests are managed on a case by case basis.

Dated: October 31, 2019.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2019–24412 Filed 11–7–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket ID NRCS–2019–0013]

Watkins Branch Watershed in Buchanan County, Virginia

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of Deauthorization of Federal Funding.

SUMMARY: NRCS gives notice of the deauthorization of Federal funding for the Watkins Branch Watershed project in Buchanan County, Virginia.

FOR FURTHER INFORMATION CONTACT: John Bricker, Virginia State Conservationist, NRCS, 1606 Santa Rosa Road, Suite 209, Richmond, Virginia 23229. Telephone (804) 287–1691 or email: *Jack.Bricker@va.usda.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Watershed Protection and Flood Prevention Act of 1954 (Pub. L. 83–566) and NRCS Guidelines (7 CFR part 622), a determination has been made by John Bricker that the proposed works of improvement for the Watkins Branch Watershed project will not be installed. The sponsoring local organizations have concurred in this determination and agree that Federal funding should be deauthorized for the project. Information regarding this determination may be obtained from John Bricker at the above telephone number.

The action does not constitute a major Federal action that would significantly affect the quality of the human environment, individually or cumulatively. Therefore, an environmental assessment or environmental impact statement is not needed for this action. No administrative action on implementation of the proposed deauthorization will be taken until 60 days after the date of this publication in the **Federal Register**.

Catalog of Federal Domestic Assistance: Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Executive Order 12372 regarding State and local clearinghouse review of Federal and federally assisted programs and project is applicable.

John A. Bricker,

VA State Conservationist, Natural Resources Conservation Service.

[FR Doc. 2019–24447 Filed 11–7–19; 8:45 am]

BILLING CODE 3410–16–P

COMMISSION ON CIVIL RIGHTS

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

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Indiana Advisory Committee (Committee) will hold community forum on Saturday, November 16, 2019, from 2:30–5:30 p.m. Eastern Time for the purpose of discussing the civil rights implications of indoor and outdoor lead exposure in the state.

DATES: The meeting will be held on Saturday November 16, 2019, from 2:30–5:30 p.m. Eastern Time.

Location: Evansville Public Library, Browning Event Room A, 200 SE Martin Luther King, Jr. Blvd., Evansville, IN 47713.

Public Call Information: Dial: 800–367–2403 Conference ID: 9850484.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or 312–353–8311.

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

Members of the public are also entitled to submit written comments; the comments must be received within 30 days following the meeting. Written comments may be mailed to the Advisory Committee Management Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or

emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Committee Management Office at (312) 353–8311.

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

Agenda

Welcome and Introductions
Discussion: Lead Poisoning of Indiana's Children
Public Comment
Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of a logistical challenge with the meeting location.

Dated: November 4, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–24352 Filed 11–7–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–866]

Sodium Sulfate Anhydrous From Canada: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Negative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that sodium sulfate anhydrous (sodium sulfate) from Canada is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable November 8, 2019.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0698.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on April 24, 2019.[1] On August 15, 2019, Commerce postponed the preliminary determination of this investigation, and the revised deadline is now October 24, 2019.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II 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 the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is sodium sulfate from Canada. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.* Commerce is preliminarily not modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily finds that critical circumstances do not exist for Saskatchewan Mining and Minerals Inc. (SMM), or for all other producers and exporters. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for SMM, the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for SMM is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

[1] *See Sodium Sulfate Anhydrous from Canada: Initiation of Less-Than-Fair-Value Investigation,* 84 FR 17138 (April 24, 2019) (*Initiation Notice*).

[2] *See Sodium Sulfate Anhydrous from Canada: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 84 FR 43580 (August 21, 2019).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Sodium Sulfate Anhydrous from Canada'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice,* 84 FR at 17139.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Saskatchewan Mining and Minerals Inc	9.85
All Others	9.85

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for SMM will be equal to the company-specific estimated weighted-average dumping margin determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is SMM, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for SMM; and (3) the cash deposit rate for all other producers or exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[6] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation 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.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. 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. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On October 1, 2019, and October 2, 2019, pursuant to 19 CFR 351.210(e), SMM and the petitioners requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[7] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.[8]

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: October 24, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers sodium sulfate (Na_2SO_4) (Chemical Abstracts Service (CAS) Number 7757–82–6) that is anhydrous (*i.e.,* containing no water), regardless of purity, grade, color, production method, and form of packaging, in which the percentage of particles between 20 mesh and 100 mesh, based on U.S. mesh series screens, ranges from 10–95% and the percentage of particles finer than 100 mesh, based on U.S. mesh series screens, ranges from 5–90%.

Excluded from the scope of this investigation are specialty sodium sulfate anhydrous products, which are products whose particle distributions fall outside the described ranges. Glauber's salt ($Na_2SO_4{\cdot}10H_2O$), also known as sodium sulfate decahydrate, an intermediate product

[6] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[7] *See* SMM's Letter, ''Antidumping Duty Investigation of Sodium Sulfate Anhydrous from Canada: Request for Postponement of Final Determination and Provisional Measures Period,'' dated October 1, 2019; *see also* Petitioners' Letter, ''Sodium Sulfate Anhydrous from Canada: Petitioner's Consent to Postponement of the Final Determination,'' dated October 2, 2019.

[8] *See* section 735(b)(2) of the Act.

in the production of sodium sulfate anhydrous that has no known commercial uses, is not included within the scope of the investigation, although some end-users may mistakenly refer to sodium sulfate anhydrous as Glauber's salt. Other forms of sodium sulfate that are hydrous (*i.e.,* containing water) are also excluded from the scope of the investigation.

The merchandise subject to this investigation is classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 2833.11.5010. Subject merchandise may also be classified under 2833.11.1000, 2833.11.5050, and 2833.19.0000. Although the HTSUS subheadings and CAS registry number are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–24392 Filed 11–7–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–882]

Certain Cold-Rolled Steel Flat Products From the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review; 2017

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that POSCO received countervailable subsidies that are above *de minimis* and that Hyundai Steel Co., Ltd. (Hyundai Steel) received countervailable subsidies that are *de minimis.* The period of review (POR) is January 1, 2017 through December 31, 2017. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 8, 2019.

FOR FURTHER INFORMATION CONTACT: Yasmin Bordas or Moses Song, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3813 and (202) 482–7885, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 15, 2018, Commerce published a notice of initiation of an administrative review of the countervailing duty order on certain cold-rolled steel flat products (cold-rolled steel) from the Republic of Korea.[1] On July 8, 2019, Commerce extended the deadline for the preliminary results of this review to no later than November 1, 2019.[2] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included at the 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 and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The merchandise covered by the order is cold-rolled steel. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[4] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Companies Not Selected for Individual Review

The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any zero, *de minimis,* or rates based entirely on facts available. In this review, the only preliminary subsidy rate above *de minimis* is the rate calculated for POSCO. Therefore, for the companies for which a review was requested that were not selected as mandatory respondents, for which we did not receive a timely request for withdrawal of review, and for which we are not finding to be cross-owned with the mandatory company respondents, we are applying the subsidy rate calculated for POSCO.

Preliminary Results of Review

In accordance with 19 CFR 351.224(b)(4)(i), we calculated individual subsidy rates for Hyundai Steel and POSCO. For the POR, we preliminarily determine that the net subsidy rates for the producers/exporters under review to be as follows:

Company	Subsidy rate (percent *ad valorem*)
POSCO[5]	0.59
Hyundai Steel Co., Ltd	0.45
Dongbu Steel Co., Ltd	0.59
Dongbu Incheon Steel Co., Ltd	0.59
Dongkuk Steel Mill Co., Ltd	0.59
Dongkuk Industries Co., Ltd	0.59
Euro Line Global Co., Ltd	0.59

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 57411, 57418 (November 15, 2018).

[2] *See* Memorandum, ''Certain Cold-Rolled Steel Flat Products from the Republic of Korea: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2017,'' dated July 8, 2019.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review; 2017: Certain Cold-Rolled Steel Flat Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Company	Subsidy rate (percent *ad valorem*)
Hanawell Co., Ltd	0.59
Hankum Co., Ltd	0.59
Hyuk San Profile Co., Ltd	0.59
Nauri Logistics Co., Ltd	0.59
Taihan Electric Wire Co., Ltd	0.59
Union Steel Co., Ltd	0.59

Assessment Rate

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Rate

Pursuant to section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount indicated above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.[6] Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance at a date to be determined. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[7] Parties who submit case briefs or rebuttal briefs are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[8]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance using Enforcement and Compliance's ACCESS system.[9] Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce will inform parties of the scheduled date of the hearing which will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined.[10] Issues addressed during the hearing will be limited to those raised in the briefs.[11] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Parties are reminded that all briefs and hearing requests must be filed electronically using ACCESS and received successfully in their entirety by 5 p.m. Eastern Time on the due date.

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act, Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, within 120 days after publication of these preliminary results.

Notification to Interested Parties

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 19 CFR 351.222(b)(4).

Dated: November 1, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2019–24391 Filed 11–7–19; 8:45 am]

BILLING CODE 3510–DS–P

[5] We note that cross-ownership exists between POSCO, POSCO Chemtech (also known as POSCO Chemical Co., Ltd.), POSCO Nippon Steel RHF Joint Venture Co., Ltd., POSCO Processing and Service, Pohang Scrap Recycling Distribution Center Co., Ltd., and POSCO M-Tech. We also note that POSCO has an affiliated trading company through which it exported certain subject merchandise, POSCO Daewoo Corporation (also known as POSCO International Corporation). *See* Preliminary Decision Memorandum at 9.

[6] *See* 19 CFR 224(b).

[7] *See* 19 CFR 351.309(c)(1)(ii) and 351.309(d)(1).

[8] *See* 19 CFR 351.309(c)(2) and (d)(2).

[9] *See* 19 CFR 351.310(c).

[10] *See* 19 CFR 351.310.

[11] *See* 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–560–829]

Uncoated Paper From Indonesia: Preliminary Results of Countervailing Duty Administrative Review; 2018

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of uncoated paper from Indonesia during the period of review (POR) January 1, 2018 through December 31, 2018.

DATES: Applicable November 8, 2019.

FOR FURTHER INFORMATION CONTACT: William Miller, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3906.

SUPPLEMENTARY INFORMATION:

Background

On March 5, 2019, Commerce published a notice of opportunity to request an administrative review of the countervailing duty (CVD) order on uncoated paper from Indonesia covering the period January 1, 2018 through December 31, 2018.[1] Commerce received a timely request from the petitioners [2] for an administrative review of the countervailing duty order with respect to PT Anugerah Kertas Utama, PT Riau Andalan Kertas, APRIL Fine Paper Macao Offshore Limited, PT Asia Pacific Rayon, PT Sateri Viscose International, A P Fine Paper Trading (Hong Kong) Limited, and APRIL International Enterprise Pte. Ltd. (collectively, APRIL).[3] On May 29, 2019, Commerce published a notice of initiation of an administrative review of

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 7877 (March 5, 2019).

[2] Domtar Corporation, P.H. Glatfelter Company, the Packaging Corporation of America (PCA), and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (the USW) (collectively, petitioners).

[3] *See* Petitioners' Letter, ''Administrative Review of the Countervailing Duty Order on Uncoated Paper from Indonesia (POR 1/1/2018–12/31/2018)—Petitioners' Request for an Administrative Review,'' dated April 1, 2019.

the CVD order on uncoated paper from Indonesia with regard to the seven APRIL companies.[4]

On May 3, 2019, APRIL notified Commerce that APRIL will not be participating in the 2018 administrative review.[5]

Scope of the Order

The product covered by the order is certain uncoated paper from Indonesia. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) categories 4802.56.1000, 4802.56.2000, 4802.56.3000, 4802.56.4000, 4802.56.6000, 4802.56.7020, 4802.56.7040, 4802.57.1000, 4802.57.2000, 4802.57.3000, and 4802.57.4000. Some imports of subject merchandise may also be classified under 4802.62.1000, 4802.62.2000, 4802.62.3000, 4802.62.5000, 4802.62.6020, 4802.62.6040, 4802.69.1000, 4802.69.2000, 4802.69.3000, 4811.90.8050 and 4811.90.9080. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.[6]

Use of Facts Otherwise Available and Application of Adverse Inferences to APRIL

Subsequent to the initiation of this administrative review, Commerce issued the initial questionnaire in a letter to the Government of Indonesia (GOI) dated June 20, 2019.[7] APRIL failed to respond entirely to the questionnaire by the specified deadline. Additionally, the GOI did not submit requested information related to APRIL in response to Commerce's initial questionnaire. Therefore, because necessary information is not available on the record and because both APRIL and the GOI failed to respond to Commerce's request for information, we preliminarily find that the use of facts available is warranted, pursuant to section 776(a)(1) and 776(a)(2)(A), (B) and (C) of the Tariff Act of 1930, as amended (the Act). Moreover, because APRIL and the GOI did not cooperate to the best of their ability, pursuant to 776(b) of the Act, we preliminarily find that use of adverse facts available (AFA) is warranted to ensure that APRIL does not obtain a more favorable result by failing to cooperate than if it had fully complied with our request for information.

For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.[8] 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 found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version 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 of Review

We preliminarily determine the following net countervailable subsidy rate for the period January 1, 2018 through December 31, 2018:

Company	Net subsidy rate *Ad Valorem* (percent)
PT Anugerah Kertas Utama, PT Riau Andalan Kertas, APRIL Fine Paper Macao Offshore Limited, PT Asia Pacific Rayon, PT Sateri Viscose International, A P Fine Paper Trading (Hong Kong) Limited, and APRIL International Enterprise Pte. Ltd. (collectively, APRIL)	104.00

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with the preliminary results of a review within ten days of its public announcement, or if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to the sole company that is under review (*i.e.,* APRIL), in accordance with section 776 of the Act, and because our calculation of the AFA subsidy rate is outlined in the Preliminary Decision Memorandum,[9] there are no further calculations to disclose.

Public Comment

Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[10] 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.[11] Parties who submit case briefs or rebuttal briefs in this proceeding 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.[12] Case and rebuttal briefs should be filed using ACCESS.[13]

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 p.m. Eastern Time within 30 days after the date of publication of this notice.[14] 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 issues raised in the briefs. If

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 24743 (May 29, 2019).

[5] *See* APRIL's Letter, ''Uncoated Paper from Indonesia,'' dated May 3, 2019.

[6] For a complete description of the scope of the order, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review of Uncoated Paper from Indonesia; 2018,'' (Preliminary Decision Memorandum), dated concurrently with, and hereby adopted by, this notice.

[7] *See* Commerce's Letter, ''2018 Countervailing Duty Administrative Review of Certain Uncoated Paper from Indonesia: Countervailing Duty Questionnaire,'' dated June 20, 2019.

[8] *See* Preliminary Decision Memorandum.

[9] *Id.*

[10] *See* 19 CFR 351.309(c)(ii).

[11] *See* 19 CFR 351.309(d)(1).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] *See* 19 CFR 351.303.

[14] *See* 19 CFR 351.310(c).

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.[15]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of arguments raised in any written briefs, no later than 120 days after the publication of these preliminary results in the **Federal Register,** unless otherwise extended.[16]

Assessment

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuing the final results of this review, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess CVDs on all appropriate entries. Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of the final results of this review.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: November 1, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Application of Facts Available and Adverse Inferences
V. Recommendation

[FR Doc. 2019–24415 Filed 11–7–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–828]

Certain Uncoated Paper From Indonesia: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the sole producer/exporter subject to this administrative review made sales of subject merchandise below normal value. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 8, 2019.

FOR FURTHER INFORMATION CONTACT: Jacob Garten, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3342.

SUPPLEMENTARY INFORMATION:

Background

On March 5, 2019, Commerce published a notice of opportunity to request an administrative review of the antidumping duty (AD) order on certain uncoated paper (uncoated paper) from Indonesia covering the period March 1, 2018 through February 28, 2019.[1] Commerce received a timely request from the petitioners,[2] for an administrative review of the antidumping duty order with respect to APRIL Fine Paper Macao Offshore Limited, APRIL Fine Paper Trading Pte. Ltd., APRIL International Enterprise Pte. Ltd., A P Fine Paper Trading (Hong Kong) Limited, PT Anugerah Kertas Utama, PT Riau Andalan Kertas, PT Asia Pacific Rayon, and PT Sateri Viscose International (collectively, APRIL).[3] Commerce also received a timely request from APRIL for an administrative review.[4] On May 29, 2019, Commerce published a notice of initiation of an administrative review of the AD order on uncoated paper from Indonesia with regard to the eight APRIL companies.[5]

On May 3, 2019, APRIL withdrew its review request and notified Commerce that it would not participate in this administrative review.[6] The petitioners, however, have not withdrawn their request for administrative review of APRIL.

Scope of the Order

The product covered by the order is certain uncoated paper from Indonesia. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) categories 4802.56.1000, 4802.56.2000, 4802.56.3000, 4802.56.4000, 4802.56.6000, 4802.56.7020, 4802.56.7040, 4802.57.1000, 4802.57.2000, 4802.57.3000, and 4802.57.4000. Some imports of subject merchandise may also be classified under 4802.62.1000, 4802.62.2000, 4802.62.3000, 4802.62.5000, 4802.62.6020, 4802.62.6040, 4802.69.1000, 4802.69.2000, 4802.69.3000, 4811.90.8050 and 4811.90.9080. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.[7]

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available with adverse inferences (AFA) for APRIL, because this respondent notified Commerce that it would not participate in the review.

For a complete explanation of the methodology and analysis underlying the preliminary application of AFA, *see* the accompanying Preliminary Decision Memorandum. 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 found at *http://enforcement.trade.gov/frn/*. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision

[15] *Id.*

[16] *See* section 751(a)(3)(A) of the Act.

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 7877 (March 5, 2019).

[2] Domtar Corporation, P.H. Glatfelter Company, the Packaging Corporation of America (PCA), and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (the USW) (collectively, the petitioners).

[3] *See* Petitioners' Letter, ''Administrative Review of the Countervailing Duty Order on Uncoated Paper from Indonesia (POR 1/1/2018–12/31/2018)—Petitioners' Request for an Administrative Review,'' dated April 1, 2019.

[4] *See* APRIL's Letter, ''*Uncoated Paper from Indonesia,*'' dated April 1, 2019 (filed on behalf of PT Anugerah Kertas Utama (AKU), PT Riau Andalan Kertas (RAK), and APRIL Fine Paper Macao Offshore Limited (AFPM)).

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 24743 (May 29, 2019).

[6] *See* APRIL's Letter, ''Uncoated Paper from Indonesia,'' dated May 3, 2019 (withdrawing its review request and stating ''APRIL will not be participating in the above administrative review.'').

[7] For a complete description of the scope of the order, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2018–2018 Administrative Review of the Antidumping Duty Order on Certain Uncoated Paper from Indonesia'' (Preliminary Decision Memorandum), issued concurrently with and hereby adopted by this notice.

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 of the Review

As a result of this review, we preliminarily determine that the weighted-average dumping margin exists for APRIL for the period March 1, 2018 through February 28, 2019, as follows:

Exporter/producer	Margin (percent)
APRIL Fine Paper Macao Offshore Limited, APRIL Fine Paper Trading Pte. Ltd., APRIL International Enterprise Pte. Ltd., A P Fine Paper Trading (Hong Kong) Limited, PT Anugerah Kertas Utama, PT Riau Andalan Kertas, PT Asia Pacific Rayon, and PT Sateri Viscose International (collectively, APRIL)	66.82

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with the preliminary results of a review within ten days of its public announcement, or if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, there are no calculations to disclose here because, in accordance with section 776 of the Act, Commerce preliminarily applied AFA to APRIL, the sole company subject to this review, and based the AFA rate on the highest petition rate in this proceeding.[8]

Public Comment

Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[9] 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.[10] Parties who submit case briefs or rebuttal briefs in this proceeding 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.[11] Case and rebuttal briefs should be filed using ACCESS.[12]

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.[13] 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 issues raised in the 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.[14]

Commerce intends to issue the final results of this administrative review, including the results of its analysis raised in any written briefs, no later than 120 days after the publication date of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[15] The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[16] 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

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 APRIL will be that established in the final results of this review; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 2.10 percent, the all-others rate made effective by the LTFV investigation.[17] These 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)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing 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 and/or countervailing 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 the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of 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 violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and

[8] *See Certain Uncoated Paper from Australia, Brazil, the People's Republic of China, Indonesia, and Portugal: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 8608 (February 18, 2015), and accompanying Antidumping Duty Investigation Initiation Checklist: Uncoated Paper from Indonesia at 12.

[9] *See* 19 CFR 351.309(c).

[10] *See* 19 CFR 351.309(d).

[11] *See* 19 CFR 351.309(c)(2) and (d)(2).

[12] *See* 19 CFR 351.303.

[13] *See* 19 CFR 351.310(c).

[14] *Id.*

[15] *See* 19 CFR 351.212(b)(1).

[16] *See* section 751(a)(2)(C) of the Act.

[17] *See Order,* 81 FR at 11174.

777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: November 1, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Application of Facts Available and Adverse Inferences
V. Recommendation

[FR Doc. 2019–24393 Filed 11–7–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the Civil Nuclear Trade Advisory Committee

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

ACTION: Notice of a Partially Closed Federal Advisory Committee Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the Civil Nuclear Trade Advisory Committee (CINTAC). This notice amends a previous notice published in the **Federal Register** on October 28, 2019. This amended notice cites the specific exemptions of the Government in the Sunshine Act, as the basis for partial closure of the previously noticed meeting.

DATES: The meeting is scheduled for Tuesday, November 12, 2019, from 8:30 a.m. to 4:00 p.m. Eastern Standard Time (EST). The deadline for members of the public to register to participate, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. Eastern Standard Time (EST) on Thursday, November 7, 2019.

ADDRESSES: The meeting will be held at the U.S. Department of Commerce, Herbert C. Hoover Building, Commerce Research Library, 1401 Constitution Ave NW, Washington, DC 20230. Requests to register to participate (including to speak or for auxiliary aids) and any written comments should be submitted to: Mr. Devin Horne, Office of Energy & Environmental Industries, International Trade Administration, Room 28018, 1401 Constitution Ave. NW, Washington, DC 20230. (Fax: 202–482–5665; email: *devin.horne@trade.gov*). Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Mr. Devin Horne, Office of Energy & Environmental Industries, International Trade Administration, Room 28018, 1401 Constitution Ave. NW, Washington, DC 20230. (Phone: 202–482–0775; Fax: 202–482–5665; email: *devin.horne@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background: The CINTAC was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), in response to an identified need for consensus advice from U.S. industry to the U.S. Government regarding the development and administration of programs to expand United States exports of civil nuclear goods and services in accordance with applicable U.S. laws and regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities will affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

The Department of Commerce renewed the CINTAC charter on August 10, 2018. This meeting is being convened under the sixth charter of the CINTAC.

Topics to be considered: The agenda for the Tuesday, November 12, 2019 CINTAC meeting is as follows:

Closed Session (8:30 a.m.–3:00 p.m.)—Discussion of matters determined to be exempt from the provisions of the Federal Advisory Committee Act relating to public meetings found in 5 U.S.C. App. §§ (10)(a)(1) and 10(a)(3). The session will be closed to the public pursuant to Section 10(d) of FACA as amended by Section 5(c) of the Government in Sunshine Act, Public Law 94–409, and in accordance with Section 552b(c)(4) and Section 552b(c)(9)(B) of Title 5, United States Code, which authorize closure of meetings that are ''likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential'' and ''likely to significantly frustrate implementation of a proposed agency action,'' respectively. The part of the meeting that will be closed will address (1) nuclear cooperation agreements; (2) encouraging ratification of the Convention on Supplementary Compensation for Nuclear Damage; (3) a briefing on civil nuclear cooperation with China; and (4) identification of specific trade barriers impacting the U.S. civil nuclear industry.

Public Session (3:00 p.m.–4:00 p.m.)—Opportunity to Hear from Members of the Public.

Members of the public wishing to attend the public session of the meeting must notify Mr. Devin Horne at the contact information above by 5:00 p.m. EST on Thursday, November 7, 2019 in order to pre-register to participate. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted but may not be possible to fill. A limited amount of time will be available for brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 60 minutes. Individuals wishing to reserve speaking time during the meeting must contact Mr. Horne and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5:00 p.m. EST on Thursday, November 7, 2019. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, ITA may conduct a lottery to determine the speakers.

Any member of the public may submit written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to the Civil Nuclear Trade Advisory Committee, Office of Energy & Environmental Industries, Room 28018, 1401 Constitution Ave. NW, Washington, DC 20230. For consideration during the meeting, and to ensure transmission to the Committee prior to the meeting, comments must be received no later than 5:00 p.m. EST on Thursday, November 7, 2019. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

Dated: October 22, 2019.

Devin Horne,

Designated Federal Officer, Office of Energy and Environmental Industries.

[FR Doc. 2019–24403 Filed 11–7–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV123]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel will hold a public webinar meeting, jointly with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Advisory Panel.

DATES: The meeting will be held on Friday, November 22, 2019, from 9 a.m. until 12 p.m.

ADDRESSES: The meeting will be held via webinar, which can be accessed at: *http://mafmc.adobeconnect.com/fsb_ap_nov2019/.* Meeting audio can also be accessed via telephone by dialing 1–800–832–0736 and entering room number 5068871.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council's Summer Flounder, Scup, and Black Sea Bass Advisory Panel will meet via webinar jointly with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Advisory Panel. The purpose of this meeting is to review staff and Monitoring Committee recommendations for 2020 recreational management measures for summer flounder, scup and black sea bass, and to provide Advisory Panel input on the 2020 recreational management measures for all three species.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: November 4, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–24364 Filed 11–7–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV124]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting (webinar).

SUMMARY: Participants in the Pacific Fishery Management Council's (Pacific Council's) 2019 groundfish stock assessment process will hold a meeting via webinar to review and evaluate the 2019 stock assessment review (STAR) process. The goal of the webinar is to solicit process improvements to recommend for future groundfish stock assessments and STAR panel reviews. Process recommendations will be provided to the Pacific Council at their March 2020 meeting in Rohnert Park, CA. The webinar meeting is open to the public.

DATES: The Groundfish Stock Assessment Process Review webinar will be held Friday, December 13, 2019, from 8:30 a.m. to 5 p.m. (Pacific Standard Time) or until business for the day has been completed.

ADDRESSES: The Groundfish Stock Assessment Process Review meeting will be held by webinar. To attend the webinar, (1) join the meeting by visiting this link *http://www.gotomeeting.com/webinar;* (2) enter the webinar ID: 729–240–515, and (3) enter your name and email address (required). After logging into the webinar, please (1) dial this TOLL number: 1–562–247–8321 (not a toll-free number); (2) enter the attendee phone audio access code: 221–339–854; and (3) then enter your audio phone pin (shown after joining the webinar). NOTE: We have disabled mic/speakers as an option and require all participants to use a telephone or cell phone to participate. Technical Information and System Requirements: PC-based attendees are required to use Windows® 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, Android™ phone or Android tablet (See the *https://www.gotomeeting.com/webinar/ipad-iphone-android-webinar-apps*). You may send an email to Mr. Kris Kleinschmidt at *Kris.Kleinschmidt@noaa.gov* or contact him at 503–820–2280, extension 411 for technical assistance. A public listening station will also be available at the Pacific Council office.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Staff Officer, Pacific Fishery Management Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The purpose of the Groundfish Stock Assessment Process Review webinar meeting is to review the 2019 groundfish stock assessment and STAR Panel process and recommend process improvements for future groundfish stock assessments and STAR Panel meetings.

No management actions will be decided by the participants attending the Groundfish Stock Assessment Process Review webinar. The webinar participants' role will be the development of recommendations and a report for consideration by the Pacific Council's Scientific and Statistical Committee, other Pacific Council advisors, and the Pacific Council at the March 2020 meeting in Rohnert Park, CA.

Although nonemergency issues not contained in the meeting agendas may be discussed, those issues may not be the subject of formal action during this webinar. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent of the webinar participants to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov,* (503) 820–2411), at least 10 days prior to the meeting date.

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

Dated: November 4, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–24365 Filed 11–7–19; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete services from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: December 8, 2019.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following services are proposed for deletion from the Procurement List:

Services

Service Type: Administrative Services
Mandatory for: GSA, Sacramento PBS: Sacramento Field Office, Sacramento, CA
Mandatory Source of Supply: Crossroads Building Services, Inc.—Deleted, Sacramento, CA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR

Service Type: Administrative Services
Mandatory for: GSA, Federal Technology Service: 10304 Eaton Place, Fairfax, VA
Mandatory Source of Supply: ServiceSource, Inc., Oakton, VA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR

Service Type: Custodial Services
Mandatory for: Harley O. Staggers Federal Building, Morgantown, WV
Mandatory Source of Supply: PACE Enterprises of West Virginia, Inc., Morgantown, WV
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR

Patricia Briscoe,

Deputy Director, Business Operations (Pricing and Information Management).

[FR Doc. 2019–24389 Filed 11–7–19; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes services from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date deleted from the Procurement List:* December 08, 2019.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 10/4/2019, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product and service listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product and service deleted from the Procurement List.

End of Certification

Accordingly, the following product and service are deleted from the Procurement List:

Product

NSN—Product Name:
8140–01–063–7681—Grommet
Mandatory Source of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: W40M RHCO–ATLANTIC USAHCA, FORT BELVOIR, VA

Service

Service Type: Janitorial/Custodial
Mandatory for: USDA, Forest Service: 4886 Cottage Grove Avenue, Humboldt Nursery, McKinleyville, CA
Contracting Activity: AGRICULTURE, DEPARTMENT OF, PROCUREMENT OPERATIONS DIVISION

Patricia Briscoe,

Deputy Director, Business Operations (Pricing and Information Management).

[FR Doc. 2019–24388 Filed 11–7–19; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Florida Keys Coastal Storm Risk Management Study

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

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 Monroe County, Florida, from hurricanes and other storms with their associated wind, storm surge, and coastal flooding.

DATES: Scoping comments are due by December 9, 2019.

ADDRESSES: The public is invited to submit NEPA scoping comments to Ms. Kathy Perdue, Department of the Army, U.S. Army Corps of Engineers, Norfolk District, Fort Norfolk, 803 Front St., Norfolk, VA 23510 or via email: *Kathy.S.Perdue@usace.army.mil.* The project title and the commenter's

contact information should be included with submitted comments.

FOR FURTHER INFORMATION CONTACT: Ms. Kathy Perdue, (757) 201–7218.

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) and Section 106 of the National Historic Preservation Act of 1966, as amended, 16 U.S.C. 470f as implemented by Advisory Council on Historic Preservation regulations (36 CFR part 800). The study authority is Public Law 84–71 of 1955 which authorizes 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 the vulnerability of critical infrastructure: the U.S. Route 1 corridor, and local development and population centers, to storm damage from major storms. Coastal flooding is exacerbated by Relative Sea Level Change, which also amplifies storm surge due to higher waters. These trends are expected to continue and worsen without intervention. Measures being considered include structural, nonstructural and natural and nature-based features such as road stabilization, buyouts/elevations of buildings, dry and wet flood-proofing of buildings, early warning systems, mangrove restoration, and living shorelines.

USACE is the lead federal agency and Monroe County is the non-federal sponsor for the study effort. The Feasibility 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. The Study Area consists of all of the Florida Keys, a 123-mile-long chain of islands extending into the Gulf of Mexico to the southern tip of Florida. Several alternatives are currently being considered, including a no action alternative and various combinations of structural measures, nonstructural measures, and natural and nature based features for reducing risks and damages caused by coastal storms in the Study Area in Monroe County, Florida.

Scoping/Public Involvement. Two public NEPA scoping meetings were held in Monroe County. On September 11, 2019, from 5 p.m.—7 p.m. at the Key Largo Board of County Commissioners Room, Murray Nelson Government Center, 102050 Overseas Hwy, Key Largo, FL 33037. A second public meeting was held on September 12, 2019, at the Key West Commission Room, Harvey Government Center, 1200 Truman Avenue, Key West, Florida 33040. Federal, state, and local agencies, Indian tribes, and the public are invited to provide scoping comments to identify issues and potentially significant effects to be considered in the analysis.

Diana M. Holland,

Major General, U.S. Army, Commander, South Atlantic Division.

[FR Doc. 2019–24417 Filed 11–7–19; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2019–HQ–0019]

Submission for OMB Review; Comment Request

AGENCY: The Office of the Under Secretary of the Navy, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 9, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Personalized Recruiting for Immediate and Delayed Enlistment Modernization (PRIDE Mod); OMB Control Number 0703–0062.

Type of Request: Extension.

Number of Respondents: 60,000.

Responses per Respondent: 1.

Annual Responses: 60,000.

Average Burden per Response: 1 hour.

Annual Burden Hours: 60,000.

Needs and Uses: The information collection requirement is necessary to support the U.S. Navy's process to recruit and access persons for naval service.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this *Federal Register* document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 5, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24435 Filed 11–7–19; 8:45 am]

BILLING CODE 5001–06–P

ELECTION ASSISTANCE COMMISSION

Board of Advisors; Notice of Meeting

AGENCY: U.S. Election Assistance Commission.

ACTION: Notice of Public Quarterly Conference Call for EAC Board of Advisors.

DATES: Monday, November 18, 2019, 3:00–4:00 p.m. (EDT).

ADDRESSES: EAC Board of Advisers Quarterly Conference Call.

To listen and monitor the event as an attendee:

1. Go to *https://zoom.us/j/9770268359?pwd=WW4wdnJMdkpJc25WZlFRZXF1UXJGUT09.*

2. *Enter Meeting ID: 977 026 8359, Password:* EACPass1.

To join the audio conference only:

1. Call a number below and enter the meeting ID. US TOLL FREE: +1–888–788–0099 or +1–877–853–5247, Meeting ID: 977 026 8359.

FOR FURTHER INFORMATION CONTACT: Bert Benavides, Telephone: (301) 563–3937.

For assistance joining the event: Contact the host, Steve Uyak at *suyak@eac.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. Appendix 2), the U.S. Election Assistance Commission (EAC) Board of Advisors will conduct a conference call to discuss current EAC activities.

Agenda: The Board of Advisors (BOA) will receive updates of EAC activities; Vote on distributed resolutions; Annual Meeting and BOA Committee/Sub-Committee Updates. The Board of Advisors will discuss the next Quarterly BOA Conference Call.

Members of the public may submit relevant written statements to the Board of Advisors with respect to the meeting no later than 10:00 a.m. EDT on Monday, November 18, 2019. Statements may be sent via email to *facaboards@eac.gov,* via standard mail addressed to the U.S. Election Assistance Commission, 1335 East West Highway, Suite 4300, Silver Spring, MD 20910, or by fax at 301–734–3108.

This conference call will be open to the public.

Nichelle S. Williams,

Director of Research, U.S. Election Assistance Commission.

[FR Doc. 2019–24416 Filed 11–7–19; 8:45 am]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection: Contracting

AGENCY: Bonneville Power Administration, Department of Energy.

ACTION: Notice of information collection; request for comments.

SUMMARY: The Department of Energy (DOE), Bonneville Power Administration (BPA), invites public comment on a collection of information that BPA is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995.

DATES: Comments regarding this proposed information collection must be received on or before January 7, 2020.

ADDRESSES: Written comments may be sent to Bonneville Power Administration, Attn: Laura McCarthy, CGI–7, PO Box 3621, Portland, OR 97208–3621, or by fax Attn: Laura McCarthy, CGI–7, at 503–230–4619, or by email at *ljmccarthy@bpa.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Attn: Laura McCarthy, CGI–7, PO Box 3621, Portland, OR 97208–3621, or by fax Attn: Laura McCarthy, CGI–7 at 503–230–4619, or by email at *ljmccarthy@bpa.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. This information collection request contains:

(1) *OMB No.:* New; (2) *Information Collection Request Title:* Contracting; (3) *Type of Request:* Existing collections without OMB Control Number; (4) *Purpose:* This information collection is associated with BPA's management and oversight of contracting requirements in fulfillment of BPA vendor contracts. Non-employees, contractors, and the general public complete the following forms: BPA F 4220.04—Subcontracting Report for Individual Contracts; BPA F 4220.5—Amendment of Solicitation/Modification of Contract/Order; BPA F 4220.52—Solicitation, Offer, and Award for Construction; and BPA F 4220.55—Solicitation/Contract/Order for Services and/or Items; (5) *Estimated Number of Respondents:* 3,370; (6) *Annual Estimated Number of Respondents;* 3,370; (7) *Annual Estimated Number of Burden Hours:* 158; and (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* 0.

Statutory Authority: The Bonneville Project Act codified at 16 U.S.C. 832; the Federal Columbia River Transmission System Act of 1974; and the Pacific Northwest Electric Power Planning and Conservation Act.

Signed on the 2nd day of October, 2019.

Candice D. Palen,

Information Collection Clearance Manager.

[FR Doc. 2019–24428 Filed 11–7–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Lighting R&D Opportunities

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI) number DE–FOA–0002160 regarding the DOE Building Technologies Office (BTO) Lighting Research and Development (R&D) Program. The purpose of this RFI is to seek broad stakeholder input to inform the strategic direction of the DOE Lighting Research & Development (R&D) Program and resulting portfolio. The purpose of issuing this RFI is to better understand how lighting research priorities and goals can be refined to reflect evolving technology needs and to inform related R&D technologies.

DATES: Responses to the RFI must be received by December 19, 2019.

ADDRESSES: Interested parties are to submit comments electronically to *LightingRFI@netl.doe.gov.* Include ''Lighting RFI'' in the subject of the title. Responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Responses must be provided as a Microsoft Word (.docx) attachment to the email, and no more than 10 pages in length, 12-point font, 1-inch margins. Only electronic responses will be accepted. The complete RFI document is located at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to *LightingRFI@netl.doe.gov,* or Brian Walker, 202–586–0650, *brian.walker@ee.doe.gov.* Further instruction can be found in the RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: EERE is specifically interested in information on three different topic areas: (1) Provide critical input on current Lighting Program direction, activities, and opportunities; (2) Identify impactful lighting R&D opportunities within general illumination that are absent (or

under-represented) in the 2018 DOE Solid-State Lighting (SSL) R&D Opportunities (RDO) document; and (3) Identify impactful lighting R&D opportunities whose immediate applications are beyond general illumination but have the potential to help save energy in the built environment. The RFI is available at*: https://eere-exchange.energy.gov/.*

Confidential Business Information

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

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

Signed in Washington, DC, on November 1, 2019.

David Nemtzow,

Director, Building Technologies Office.

[FR Doc. 2019–24430 Filed 11–7–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC20–13–000.

Applicants: Electric Energy, Inc., GridLiance HeartLand LLC.

Description: Joint Application Under Section 203 of the Federal Power Act of GridLiance HeartLand LLC, and Electric Energy, Inc.

Filed Date: 11/1/19.

Accession Number: 20191101–5299.

Comments Due: 5 p.m. ET 11/22/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–280–001.

Applicants: Skookumchuck Wind Energy Project, LLC.

Description: Tariff Amendment: Amendment to MBR Authority Application and Initial Baseline Tariff Filing to be effective 12/1/2019.

Filed Date: 11/1/19.

Accession Number: 20191101–5202.

Comments Due: 5 p.m. ET 11/22/19.

Docket Numbers: ER20–293–000.

Applicants: Brickyard Hills Project, LLC.

Description: Tariff Cancellation: Notice of Cancellation of Market-Based Tariff for Brickyard Hills Project to be effective 11/2/2019.

Filed Date: 11/1/19.

Accession Number: 20191101–5276.

Comments Due: 5 p.m. ET 11/22/19.

Docket Numbers: ER20–294–000.

Applicants: Sun Streams, LLC.

Description: § 205(d) Rate Filing: Shared Facilities Common Ownership Agreement to be effective 11/2/2019.

Filed Date: 11/1/19.

Accession Number: 20191101–5280.

Comments Due: 5 p.m. ET 11/22/19.

Docket Numbers: ER20–295–000.

Applicants: Interstate Power and Light Company.

Description: § 205(d) Rate Filing: Interstate Power and Light Company Wholesale Formula Rate Application to be effective 12/31/2019.

Filed Date: 11/1/19.

Accession Number: 20191101–5281.

Comments Due: 5 p.m. ET 11/22/19.

Docket Numbers: ER20–296–000.

Applicants: Wisconsin Power and Light Company.

Description: § 205(d) Rate Filing: Wisconsin Power and Light Company Wholesale Formula Rate Application to be effective 12/31/2019.

Filed Date: 11/1/19.

Accession Number: 20191101–5282.

Comments Due: 5 p.m. ET 11/22/19.

Docket Numbers: ER20–297–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/ISA No. 4374/Queue No. AB1–037 to be effective 11/12/2019.

Filed Date: 11/4/19.

Accession Number: 20191104–5034.

Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–298–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4375; Queue No. AB1–038 to be effective 11/12/2019.

Filed Date: 11/4/19.

Accession Number: 20191104–5054.

Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–299–000.

Applicants: Duke Energy Florida, LLC.

Description: Notice of Cancellation of Jurisdictional Agreements of Duke Energy Florida, LLC.

Filed Date: 11/4/19.

Accession Number: 20191104–5061.

Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–300–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4376/Queue No. AB1–039 to be effective 11/12/2019.

Filed Date: 11/4/19.

Accession Number: 20191104–5073.

Comments Due: 5 p.m. ET 11/25/19.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF20–202–000.

Applicants: Eco Green Generation LLC.

Description: Form 556 of Eco Green Generation LLC [Clean Power #8].

Filed Date: 11/1/19.

Accession Number: 20191101–5308.

Comments Due: None Applicable.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 4, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–24421 Filed 11–7–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–280–000]

Skookumchuck Wind Energy Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Skookumchuck Wind Energy Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 25, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 4, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–24424 Filed 11–7–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–517–000]

Gulf South Pipeline Company, LP; Notice of Intent To Prepare an Environmental Assessment for the Proposed Lamar County Expansion Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Lamar County Expansion Project involving construction and operation of facilities by Gulf South Pipeline Company, LP (Gulf South), in Lamar and Forrest Counties, Mississippi. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies about issues regarding the project. The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires the Commission to discover concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of issues to address in the EA. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on December 4, 2019.

You can make a difference by submitting your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Commission staff will consider all filed comments during the preparation of the EA.

If you sent comments on this project to the Commission before the opening of this docket on September 30, 2019, you will need to file those comments in Docket No. CP19–517–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law.

Gulf South provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC website (*www.ferc.gov*) at *https://www.ferc.gov/resources/guides/gas/gas.pdf.*

Public Participation

The Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. To sign up go to *www.ferc.gov/docs-filing/esubscription.asp.*

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature, which is located on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on *eRegister.* You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP19–517–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Summary of the Proposed Project

Gulf South proposes to construct and operate 3.4 miles of 20-inch-diameter pipeline, a new delivery meter station, and a new 5,000 horsepower compressor station in Lamar and Forrest Counties, Mississippi. The Lamar County Expansion Project would provide about 200,000 dekatherm of natural gas per day to Cooperative Entergy proposed 550 megawatt combined cycle gas turbine generation facility in Lamar County. According to Gulf South, its project would allow Cooperative Entergy's Power plant to switch from coal to natural gas as a power source.

The Lamar County Expansion Project would consist of the following facilities:

- 3.4 miles of new 20-inch-diameter pipeline lateral in Lamar and Forrest Counties, Mississippi;
- New Black Creek Compressor Station at approximate station 128+08 on Gulf South's existing Index 299 pipeline in Forrest County, Mississippi; and
- New Plant Morrow Meter Station at the terminus of the new 20-inch delivery lateral in Lamar County, Mississippi.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Construction of the proposed facilities would disturb about 139 acres of land for the aboveground facilities and the pipeline. Following construction, Gulf South would maintain about 40.8 acres for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses. About 23 percent of the proposed pipeline route parallels existing pipeline, utility, or road rights-of-way.

The EA Process

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- air quality and noise;
- public safety; and
- cumulative impacts.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present Commission staffs' independent analysis of the issues. The EA will be available in electronic format in the public record through eLibrary[2] and the Commission's website (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). If eSubscribed, you will receive instant email notification when the EA is issued. The EA may be issued for an allotted public comment period. Commission staff will consider all comments on the EA before making recommendations to the Commission. To ensure Commission staff have the opportunity to address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] The EA for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

If the Commission issues the EA for an allotted public comment period, a *Notice of Availability* of the EA will be sent to the environmental mailing list and will provide instructions to access the electronic document on the FERC's website (*www.ferc.gov*). If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please return the attached ''Mailing List Update Form'' (appendix 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on General Search and enter the docket number in the Docket Number field, excluding the last three digits (*i.e.,* CP19–517). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: November 4, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–24420 Filed 11–7–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR20–4–000.

Applicants: Acacia Natural Gas, L.L.C.

Description: Tariff filing per 284.123(b),(e)+(g): Amended Statement of Operating Conditions to be effective 10/30/2019.

Filed Date: 10/30/19.

Accession Number: 201910305127.

Comments Due: 5 p.m. ET 11/20/19.

284.123(g) Protests Due: 5 p.m. ET 12/30/19.

Docket Number: PR20–5–000.

Applicants: Midcoast Pipelines (North Texas) L.P.

Description: Tariff filing per 284.123(b)(2)+(g): Petition for Rate Approval under Optional Notice Procedures to be effective 11/1/2019.

Filed Date: 11/1/19.

Accession Number: 201911015147.

Comments Due: 5 p.m. ET 11/22/19.

284.123(g) Protests Due: 5 p.m. ET 12/31/19.

Docket Numbers: RP20–133–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Compliance filing Atlantic Bridge—Permanent Release NRA Filing to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5000.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–134–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—11–1–2019 Consolidated Edison 910950 Releases to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5035.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–135–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Keyspan 510369 releases eff 11–1–19 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5038.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–136–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2019–10–31 EQT to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5045.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–137–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Rate Schedules LSS & SS–2 Tracker eff 11/1/2019—National Fuel to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5051.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–138–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Freepoint Commodities LLC to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5062.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–139–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing—Shell Energy North to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5064.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–140–000.

Applicants: Ruby Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Fuel L&U and EPC Update Filing to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5065.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–141–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—ConEd 510371 releases eff 11–1–19 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5067.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–142–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel and L&U Reimbursement Percentage Update to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5068.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–143–000.

Applicants: ETC Tiger Pipeline, LLC.

Description: § 4(d) Rate Filing: Fuel Filing on 10–31–19 to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5071.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–144–000.

Applicants: Fayetteville Express Pipeline LLC.

Description: § 4(d) Rate Filing: Fuel Filing on 10–31–19 to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5072.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–145–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Rate Schedules GSS & LSS Tracker eff 11/1/2019—Dominion to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5079.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–146–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—BUG 799989 releases eff 11–1–19 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5090.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–147–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate—CBPX to Direct Energy 800499 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5096.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–148–000.

Applicants: Sierrita Gas Pipeline LLC.

Description: § 4(d) Rate Filing: Fuel and L&U Filing to be effective 12/31/9998.

Filed Date: 10/31/19.

Accession Number: 20191031–5105.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–149–000.

Applicants: Texas Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (JERA 37702 to EDF 38315) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5106.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–150–000.

Applicants: Texas Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Gulfport releases eff 11–1–2019) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5107.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–151–000.

Applicants: Texas Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Kaiser 35448 to Tenaska 38326) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5115.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–152–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Non-Conforming Negotiated Rate Agreement Update (SoCal Nov Mar) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5122.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–153–000.

Applicants: WBI Energy Transmission, Inc.

Description: § 4(d) Rate Filing: 2019 Non-Conforming Service Agreements with Phillips & MDU to be effective 11/21/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5128.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–154–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate—PSEG contract 511047 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5132.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–155–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Constellation 51655 to Exelon 51690) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5137.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–156–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Trans Louisiana 51695 to Centerpoint 51707) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5140.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–157–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Aethon 50488, 37657 to Scona 51724, 51725) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5141.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–158–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update Filing (Conoco Nov 19) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5143.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–159–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Nov 2019 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5169.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–160–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: PCB TETLP 2019 FILING to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5172.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–161–000.

Applicants: LA Storage, LLC.

Description: § 4(d) Rate Filing: Filing of Negotiated Rate, Conforming IW Agreement (Total) to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5204.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–162–000.

Applicants: MarkWest Pioneer, L.L.C.

Description: § 4(d) Rate Filing: Amendment to Nonconforming Negotiated Rate Service Agreement to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5206.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–163–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Initial Rate Filing—Gateway Expansion Project to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5207.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–164–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—NESL_Sequent to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5217.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–165–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate—DTE Electric to Tenaska 960613 to be effective 11/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5221.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–166–000.

Applicants: Equitrans, L.P.

Description: Compliance filing Operational Purchases and Sales Report for 2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5223.

Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–167–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: AGT FRQ 2019 Filing to be effective 12/1/2019.

Filed Date: 10/31/19.

Accession Number: 20191031–5224.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–168–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Non-Conforming—Leidy Southeast_PSNC Superseding_2 to be effective 12/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5227.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–169–000.
Applicants: Trunkline Gas Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—15 to be effective 11/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5251.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–170–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: TETLP ASA DEC 2019 FILING to be effective 12/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5253.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–171–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreements Filing (EOG) to be effective 12/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5257.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–172–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20191031 Negotiated Rate to be effective 11/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5261.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–173–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—EAP Ohio 860161 Nov 1 Releases to be effective 11/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5264.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–174–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Non-Conforming Agreements Filing (Saavi_Sempra) to be effective 11/1/2019.
Filed Date: 10/31/19.
Accession Number: 20191031–5266.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–175–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 11–1–19 to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5001.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–176–000.
Applicants: Enable Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—November 1 2019 Encana 1011022 to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5051.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–177–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: Pre-Arranged/Pre-Agreed (Stipulation and Agreement of Settlement) Filing of Columbia Gulf Transmission, LLC under RP20–177.
Filed Date: 11/1/19.
Accession Number: 20191101–5056.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–178–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: Conexus Negotiated Rate Agreement to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5060.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–179–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rate—ConEd 910950 release to Sunsea 8960796 to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5061.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–180–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: TCO UGI NC Agreements to be effective 12/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5062.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–181–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: Compliance filing Destin Pipeline Company Annual Fuel Retention Adjustment.
Filed Date: 11/1/19.
Accession Number: 20191101–5063.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–182–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Boston Gas 511109 Release to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5091.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–183–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (FPL 41618, 41619 amendments and to Spire 51627) to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5095.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–184–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (BP 51411 to BP 51709, 51738) to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5096.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–185–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Osaka releases eff 11–1–2019) to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5097.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–186–000.
Applicants: Millennium Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Non-Conforming & Negotiated Rate Svc Amds—SWN to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5123.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–187–000.
Applicants: Columbia Gas Transmission, LLC.
Description: § 4(d) Rate Filing: OTRA Winter 2019 to be effective 12/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5138.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–188–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: 2019 Fuel Tracker Filing to be effective 4/1/2020.
Filed Date: 11/1/19.
Accession Number: 20191101–5142.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–189–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: 2019 Fuel Tracker Filing to be effective 4/1/2020.
Filed Date: 11/1/19.

Accession Number: 20191101–5143.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–190–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: § 4(d) Rate Filing: LAXP Interim Negotiated Rate Agreement Filing to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5144.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–191–000.
Applicants: Portland Natural Gas Transmission System.
Description: § 4(d) Rate Filing: PNGTS Westbrook Agreements Filing to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5146.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–192–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Amendments to Negotiated Rate Filings-Macquarie Energy to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5148.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–193–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Capacity Release Agreements—11/1/2019 to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5149.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–194–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Contract Adjustments for 11–1–2019 to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5160.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–195–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Equinor Release to ConEd—NRAs and NC Agreements to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5174.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–196–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—Ameren Missouri RP18–923 Settlement to be effective 1/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5226.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–197–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—CERC RP18–923 Settlement to be effective 1/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5231.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–198–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2019–11–1 Encana to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5257.
Comments Due: 5 p.m. ET 11/13/19.

Docket Numbers: RP20–199–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Volume No. 2—NJR Energy Services Company SP 353478, 353479 and 353480 to be effective 11/1/2019.
Filed Date: 11/1/19.
Accession Number: 20191101–5284.
Comments Due: 5 p.m. ET 11/13/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 4, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–24423 Filed 11–7–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ20–3–000]

City of Vernon, California; Notice of Filing

Take notice that on October 28, 2019, the City of Vernon, California submitted its tariff filing: Filing 2020 TRR and TRBAA to be effective 1/1/2020.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 18, 2019.

Dated: November 4, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–24422 Filed 11–7–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10001–78–ORD; Docket ID No. EPA–HQ–ORD–2019–0275]

Availability of the Systematic Review Protocol for the PFDA, PFNA, PFHxA, PFHxS, and PFBA IRIS Assessments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 45-day

public comment period associated with release of the Systematic Review Protocol for the perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA) Integrated Risk Information System (IRIS) assessments. This protocol document presents the methods for conducting the systematic reviews and dose response analyses for these assessments as well as summarizes the Agency's problem formulation activities. Public input will help to inform the subsequent development of draft assessments for these per- and polyfluoroalkyl substances (PFAS) chemicals.

DATES: The 45-day public comment period begins November 8, 2019 and ends December 23, 2019. Comments must be received on or before December 23, 2019.

ADDRESSES: The Systematic Review Protocol for perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA) assessments will be available via the internet on the IRIS website at *https://www.epa.gov/iris/iris-recent-additions* and in the public docket at *http://www.regulations.gov,* Docket ID No. EPA–HQ–ORD–2019–0275. Information on these chemicals is provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: For information on the docket, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202–566–1752; facsimile: 202–566–9744; or email: *Docket_ORD@epa.gov.*

For technical information on the protocol, contact Dr. James Avery, Center for Public Health & Environmental Assessment; telephone: 202–564–1494; or email: *avery.james@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information on PFAS and Systematic Review Protocols

Per- and polyfluoroalkyl substances (PFAS) are a large class of man-made chemicals widely used in consumer products and industrial processes. The basic structure of PFAS consists of a carbon chain surrounded by fluorine atoms, with different chemicals possessing different end groups. The five toxicity assessments being developed according to the scope and methods outlined in this protocol build upon several other PFAS assessments that have already been developed, and represent only one component of the broader PFAS action plan underway at the U.S. EPA (*https://www.epa.gov/pfas/epas-pfas-action-plan*).

This protocol document presents the methods for conducting the systematic reviews and dose response analyses for assessments of perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA). This includes a summary of why these specific PFAS chemicals were prioritized for evaluation, description of the objectives and specific aims of the assessments, draft PECO (Populations, Exposures, Comparators, and Outcomes) criteria, and identification of key areas of scientific complexity. Public input received on the protocol is considered during preparation of the draft assessments and any adjustments made to the protocol will be reflected in an updated version released in conjunction with the draft assessments.

II. How To Submit Technical Comments to the Docket at *http://www.regulations.gov*

Submit your comments on the Systematic Review Protocol for the PFDA, PFNA, PFHxA, PFHxS, and PFBA IRIS Assessments to Docket ID No. EPA–HQ–ORD–2019–0275, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_ORD@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The phone number is 202–566–1752.
- *Hand Delivery:* The ORD Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004.

The EPA Docket Center 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. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments on the systematic review protocol to Docket ID No. EPA–HQ–ORD–2019–0275. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *https://www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through *https://www.regulations.gov* or email that you consider to be CBI or otherwise protected. The *https://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 *https://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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Docket: Documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *https://www.regulations.gov* or hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated: October 20, 2019.

Wayne E. Cascio,

Director, Center for Public Health & Environmental Assessment.

[FR Doc. 2019–24350 Filed 11–7–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10001–84–OA]

Farm, Ranch, and Rural Communities Committee (FRRCC) Notice of Membership Solicitation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for nominations.

SUMMARY: The Environmental Protection Agency (EPA) is inviting nominations for membership on the Farm, Ranch, and Rural Communities Advisory Committee (FRRCC). The purpose of the FRRCC is to provide policy advice, information, and recommendations to the EPA Administrator on a range of environmental issues and policies that are of importance to agriculture and rural communities.

DATES: Nominations should be submitted no later than December 31, 2019.

ADDRESSES: Submit nominations electronically (preferred) with the subject line ''FRRCC Membership 2020'' to *FRRCC@epa.gov.* You may also submit nominations by hardcopy, but they must be received by the office by December 31, 2019 to be considered. Via regular mail: Hema Subramanian, Designated Federal Officer for the FRRCC, U.S. EPA, 1200 Pennsylvania Avenue NW, Mail Code 1101A, Washington, DC 20460. Via courier: Hema Subramanian, Designated Federal Officer for the FRRCC, U.S. EPA, 1200 Pennsylvania Avenue NW, William Clinton Jefferson North Building—Room 2415, Washington, DC 20460. Questions may be directed to Hema Subramanian at *FRRCC@epa.gov* or 202–564–7719. General information regarding the FRRCC can be found on the EPA website at: *www.epa.gov/faca/frrcc.* General information about Federal advisory committees at EPA is available at: *www.epa.gov/faca.*

FOR FURTHER INFORMATION CONTACT: Hema Subramanian, Designated Federal Officer for the FRRCC, U.S. EPA, 1200 Pennsylvania Avenue NW, Mail Code 1101A, Washington, DC 20460; telephone number: 202–564–7719; email address: *FRRCC@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA established the FRRCC in 2008 pursuant to the Federal Advisory Committee Act, Public Law 92–463, in order to help EPA build a more positive and proactive relationship with the agricultural industry in furtherance of EPA's mission to protect human health and the environment. The FRRCC serves as part of EPA's efforts to expand cooperative working relationships with the agriculture community and others who are interested in agricultural issues and achieving greater progress in environmental protection. The FRRCC provides advice and recommendations to the EPA Administrator on environmental issues and programs that impact, or are of concern to, farms, ranches and rural communities. Topics addressed may include food loss and waste, water or air quality issues, pesticides, toxics, emergency response, enforcement and compliance, technology and innovation, and other topics of environmental importance pertaining to agriculture and rural communities. The previous Charter for the FRRCC was scheduled to expire and therefore was renewed in 2018; however, the committee currently has no members. EPA is currently seeking 20–30 members for the committee, who will be appointed for 2–3 year terms. The membership of this committee will include a balanced representation of interested persons with relevant experience to contribute to the functions of the committee, and will be drawn from relevant sectors, including; but not limited to academia, agricultural industry, nongovernmental organizations, and state, local, and tribal governments.

The Committee expects to meet approximately twice a year, or as needed and approved by the Designated Federal Officer (DFO). Meetings will be held in Washington, DC and the EPA regions. Members serve on the Committee in a voluntary capacity. However, EPA may provide reimbursement for travel expenses associated with official government business.

II. Eligibility

Because of the nature of the issues to be discussed, it is the intent of the Agency for the majority of Committee members to be actively engaged in farming or ranching. The membership of this committee will include a balanced representation of interested persons with relevant experience to contribute to the functions of the committee and will be drawn from a variety of relevant sectors. Members may represent farmers, ranchers, and rural communities (can include large, small, crop, livestock, commodity, and specialty producers from various regions)—and their allied industries (farm groups, rural suppliers, marketers, processors, etc.); as well as the academic/research community who research environmental issues impacting agriculture, tribal agriculture groups, state, local, and tribal government, and environmental/conservation and other nongovernmental organizations. Individuals are generally appointed to serve on the FRRCC as ''Representative'' members and are thus expected to represent the points of view of a particular group (*e.g.,* an industry sector), rather than provide independent judgment and expertise. Other Federal agencies and other sectors as appropriate may be invited to attend or provide presentations at committee meetings as non-members. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

Per an October 31, 2017 EPA Directive, ''*Strengthening and Improving Membership on EPA Federal Advisory Committees,*'' members of EPA Federal advisory committees cannot concurrently receive EPA grants, either as principal investigator or co-investigator, or be in a position that otherwise would reap substantial direct benefit from an EPA grant. This principal does not apply to state, tribal, or local government agency recipients of EPA grants.

In selecting committee members, EPA will consider each candidate's qualifications including, but not limited to, on whether the candidate is:

- Is actively engaged in farming.
- Occupies a senior position within their organization.
- Holds leadership positions in ag-related organizations, businesses and/or workgroups.
- Has broad agricultural experience regardless of their current position.
- Has experience working on issues where building consensus is necessary.
- Has membership in professional societies, broad-based networks or the equivalent.
- Has extensive experience in the environmental field dealing with agricultural issues.
- Provides services to producers.
- Is involved in processing, retailing, manufacturing and distribution of agricultural products.

• Possesses a professional knowledge of agricultural issues and environmental policy.

• Possesses a demonstrated ability to examine and analyze complicated environmental issues with objectivity and integrity.

• Possesses excellent interpersonal as well as oral and written communication skills.

• Possesses an ability and willingness to participate in a deliberative and collaborative process.

In addition, well-qualified applicants must be prepared to process a substantial amount of complex and technical information and have the ability to volunteer several hours per month to the Committee's activities, including participation in teleconference meetings and preparation of text for Committee reports.

III. Nominations

Any interested person or organization may submit the names of qualified persons, including themselves. To be considered, all nominations should include the information requested below:

• Current contact information for the nominee, including the nominee's name, organization (and position within that organization), business address, email address, and daytime telephone number(s).

• A brief statement describing the nominee's interest and availability in serving on the FRRCC. Please also include the following information, as available: (1) The nominee's ability to serve as a ''Representative'' member and represent the point of view of a group (*e.g.,* an industry sector) rather than provide independent judgment and expertise; (2) if the nominee currently receives funding from an EPA grant; (3) if the nominee has any prior/current service on Federal advisory committees, and the number of years.

• Résumé or curriculum vitae detailing the nominee's background, experience and qualifications and other relevant information.

Letters of support and recommendation will be accepted but are not mandatory. To help the agency evaluate the effectiveness of its outreach efforts, please indicate how you learned of this nomination opportunity.

Dated: October 25, 2019.

Elizabeth (Tate) Bennett,

Agriculture Advisor to the Administrator, Associate Administrator, Office of Public Engagement and Environmental Education.

[FR Doc. 2019–24348 Filed 11–7–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9047–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–5632 or *https://www.epa.gov/nepa/*.

Weekly receipt of Environmental Impact Statements

Filed 10/28/2019 10 a.m. ET Through 11/04/2019 10 a.m. ET

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search*.

EIS No. 20190268, Final Supplement, CHSRA, CA, Fresno to Bakersfield Section: Locally Generated Alternative Combined Supplemental Record of Decision and Final Supplemental Environmental Impact Statement, Contact: Dan McKell 916–330–5668

Pursuant to 23 U.S.C. 139(n)(2), CHSRA has issued a combined FEIS and ROD. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

EIS No. 20190269, Final, USFS, BLM, ID, Proposed Dairy Syncline Mine and Reclamation Plan, Review Period Ends: 12/09/2019, Contact: Bill Stout 208–478–6367

Dated: November 4, 2019.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2019–24351 Filed 11–7–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that the Director, Centers for Disease Control and Prevention (CDC), has delegated to the Director, Office of Science, Deputy Director for Public Health Science and Surveillance, CDC, and the Director, Office of Technology and Innovation, Office of Science, Deputy Director for Public Health Science and Surveillance, CDC, without the authority to redelegate, all authorities to administer and make decisions regarding the invention and patent program of CDC and the authority to make determinations of rights in inventions and patents in which CDC and the Department of Health and Human Services (HHS) have an interest.

This delegation excludes the authority under 35 U.S.C. 203 (March-in Rights) and the authority to submit reports to Congress.

In addition, this delegation excludes those authorities under the Stevenson-Wydler Technology Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation.

The exercise of this authority must be in accordance with applicable laws, regulations, and policies and instructions from the Office of Government Ethics, U.S. Office of Personnel Management, and HHS.

2

This delegation supersedes the Delegation of Authority Concerning Patents and Inventions dated November 14, 2012, from the Director, CDC.

This delegation became effective on October 23, 2019. In addition, the Director, CDC, hereby adopts any actions taken that involve the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: November 5, 2019.

Robert K. McGowan,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2019–24402 Filed 11–7–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the West Valley Demonstration Project in West Valley, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Grady Calhoun, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone: (513) 533–6800. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION: On October 25, 2019, as provided for under 42 U.S.C. 7384*l*(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

''All Atomic Weapons Employees who worked at the West Valley Demonstration Project in West Valley, New York, during the period from January 1, 1969, through December 31, 1973, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.''

This designation will become effective on November 24, 2019, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

John J. Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2019–24445 Filed 11–7–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Y–12 Plant in Oak Ridge, Tennessee, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Grady Calhoun, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone: (513) 533–6800. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION: On October 25, 2019, as provided for under 42 U.S.C. 7384*l*(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

''All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Y–12 Plant in Oak Ridge, Tennessee, during the period between January 1, 1977, through July 31, 1979, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.''

This designation will become effective on November 24, 2019, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

John J. Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2019–24446 Filed 11–7–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0019]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 7, 2020.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0019–60D and project title for reference, to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: Project Abstract Summary.

Type of Collection: Revision of a currently approved collection.

OMB No.: 4040–0019.

Abstract: The Project Abstract Summary form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use Project Abstract Summary form for grant programs not required to collect all the data that is required on the SF–424 core data set and form.

Type of respondent: Project Abstract Summary form is used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review.

ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Project Abstract Summary	Grant applicants	3,467	1	1	3,467
Total		3,467		1	3,467

Dated: November 1, 2019.

Sherrette Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–24360 Filed 11–7–19; 8:45 am]

BILLING CODE 4150–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Study Section Member Conflict Review Panel.

Date: November 21, 2019.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Room 2120, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Anna Ghambaryan, M.D., Ph.D. Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892, 301–443–4032, *anna.ghambaryan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: November 4, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24356 Filed 11–7–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance

AGENCY: National Institutes of Health, HHS.

ACTION: Request for comments.

SUMMARY: The National Institutes of Health (NIH) is seeking public comments on a DRAFT NIH Policy for Data Management and Sharing and supplemental DRAFT guidance. The purpose of this DRAFT Policy and supplemental DRAFT guidance is to promote effective and efficient data management and sharing to further NIH's commitment to making the results and accomplishments of the research it funds and conducts available to the public.

DATES: To ensure that your comments will be considered, please submit your response to this Request for Comments no later than January 10, 2020.

ADDRESSES: Comments may be submitted online at: *https://osp.od.nih.gov/draft-data-sharing-and-management.*

FOR FURTHER INFORMATION CONTACT: Andrea Jackson-Dipina, Dr.PH, Director of the Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, *jacksondipinaac@od.nih.gov*.

SUPPLEMENTARY INFORMATION:

Background

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which provides opportunity for public comment on proposed projects, we do not see this information collection as sensitive or controversial in nature, as the information collection will enable continued Policy for Data Management and Sharing allowing the research community to more effectively continue their research and serve the public. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Sharing scientific data advances this mission by enhancing NIH's stewardship of taxpayer funds and maximizing research participants' contributions. Moreover, increasing access to scientific data resulting from NIH-funded or conducted research advances biomedical research by enabling the validation of scientific results, allowing analyses to be strengthened by combining data, facilitating reuse of hard-to-generate data, and accelerating future research.

NIH has a long history of making the products of Federally-funded research available to the public. For example, in 2003, NIH released its first *NIH Data Sharing Policy* to set the expectation that final research data would be shared from awards requesting $500,000 or more in direct costs in any single year. The *NIH Public Access Policy,* which applies to manuscripts accepted for publication after April 7, 2008, ensures that the public has access to the published results of NIH-funded or conducted research by requiring NIH researchers to submit final peer-reviewed journal manuscripts to PubMed Central. NIH also has implemented policies to facilitate sharing of certain high-value data-types, such as the 2007 *NIH Genome-Wide Association Studies Policy* and the 2014 *NIH Genomic Data Sharing Policy,* establishing expectations for sharing large-scale genomic data resulting from NIH-funded or conducted studies. To maximize critical investments in clinical research, NIH has established

policies specific to sharing clinical research data. Most recently in 2016, NIH issued the *NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information* which sets forth the expectation that NIH-funded or conducted clinical trials will be registered and have summary results information submitted to *ClinicalTrials.gov,* complementing the *HHS Final Rule for Clinical Trials Registration and Results Information Submission.*

Through this Notice, NIH is seeking public input on a trans-NIH data management and sharing policy proposal that further advances the Agency's commitment to responsible data management and sharing. Of note, NIH first announced its intent to encourage broad data sharing in 2015 with the release of the *NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research* and further stakeholder input was sought via the 2017 *Request for Information: Strategies for NIH Data Management, Sharing, and Citation.* NIH shared its initial proposed policy provisions for a future draft data management and sharing policy in 2018 through its *Request for Information on Proposed Provisions of a Draft Data Management and Sharing Policy for NIH Funded or Supported Research.* In response to the 2018 Request for Information, NIH received a total of 183 submissions from both national and international stakeholders, the majority of whom described themselves as scientific researchers or institutional officials from a variety of organizational affiliations and areas of research interest. Most respondents strongly supported data sharing and the concept of defining ''scientific data'' as encompassing the data and metadata needed to replicate and validate research findings. Additionally, respondents generally agreed that researchers should prospectively outline where, when, and how scientific data resulting from NIH-funded or conducted research will be managed and shared while allowing for data sharing exceptions, when justified. Many respondents expressed concerns about varying expectations across diverse scientific domains, the NIH Institutes, Centers, and Offices (ICOs), and Federal agencies, in addition to concerns of potential burden on the research community.

Public comments received from these Requests for Information, coupled with engagement efforts and lessons learned from other Federal agencies' data sharing policies, were considered in crafting an NIH-wide data management and sharing policy proposal. After thorough review and consideration of stakeholder input, NIH developed the current DRAFT NIH Policy for Data Management and Sharing (herein referred to as ''DRAFT Policy'') for public input which, when finalized and effective, would apply to all NIH-funded or conducted research generating scientific data, regardless of data type, size, or the requested amount of funding. NIH recognizes that while all scientific data need to be managed, not all data generated in the course of research may be necessary to validate and replicate research findings. Therefore, this DRAFT Policy proposes that applicants submit a plan outlining how scientific data are to be managed and shared. Importantly, the proposed DRAFT Policy allows for flexibility across various scientific domains by outlining minimum expectations for NIH-wide Data Management and Sharing Plans (Plans), on which NIH ICOs may build. This DRAFT Policy also proposes that Plans could be submitted at ''Just-In-Time'' and reviewed by NIH program staff, which reduces applicant burden because only those applicants likely to be funded would submit Plans. This approach may facilitate consistent evaluation across NIH ICOs as well as throughout the lifetime of the award, during which updates to Plans may be made.

Paramount to this DRAFT Policy is the incorporation of principles that respect the autonomy and privacy of research participants and protection of confidential data. Thus, in the Data Management and Sharing Plan, researchers can describe practices for responsible management and sharing of sensitive scientific data, such as those from human participants (*i.e.,* through de-identification or other protective measures), including when there should be exceptions to sharing or only limited sharing of data. These considerations are particularly germane when working with small or underserved populations. For instance, NIH recognizes that sovereign Tribal Nations may have unique data sharing concerns and the Agency has engaged these communities through Tribal Consultation sessions across the U.S. to consider their potential needs in the formation of this DRAFT Policy. NIH intends to continue conversations with Tribal Nations to develop culturally sensitive data management and sharing resources for researchers seeking to collaborate with Tribal Nations. NIH encourages comments on specific strategies for promoting responsible data management and sharing in these types of research settings, including identification of areas in which further guidance may be needed.

NIH recognizes that the deliberate flexibility of its DRAFT Policy may require additional implementation guidance. It is important to acknowledge that NIH recognizes that expectations for robust data management and sharing practices will need to be met with investments in and evolution of accompanying data infrastructure. As indicated in the *NIH Strategic Plan for Data Science,* NIH's policy development efforts are being considered in tandem with its efforts to modernize the data infrastructure ecosystem. Thus, NIH also seeks feedback on proposals for supplemental DRAFT guidance documents intended to help researchers prospectively integrate Data Management and Sharing Plans into routine research practices. The supplemental DRAFT guidance: *Allowable Costs for Data Management and Sharing* (see below) proposes the types of costs that could be considered for inclusion in a research proposal to support data sharing activities. The supplemental DRAFT guidance: *Elements of An NIH Data Management and Sharing Plan* (see below) proposes a framework by which applicants could structure Data Management and Sharing Plans, including descriptions of elements such as the data type(s), standards employed, and timelines for data sharing. NIH encourages feedback on the utility of these supplemental DRAFT guidance documents and welcomes suggestions for any additional guidance that may be helpful to the community.

Substantive input is needed to ensure future policy decisions facilitate tangible and effective data management and sharing strategies. In this Request for Comment, NIH seeks public input on its proposed DRAFT NIH Policy for Data Management and Sharing and supplemental DRAFT guidance documents, including ways to promote access to research findings while minimizing burden on the research community. Feedback obtained through this Notice and other outreach efforts will help inform a final NIH Policy for Data Management and Sharing, which upon the effective date, would replace the 2003 *NIH Data Sharing Policy.*

Request for Comments

NIH encourages the public to provide comments on any aspect of the DRAFT Policy and supplemental DRAFT guidance, described below.

I. DRAFT NIH Policy for Data Management and Sharing,

II. Supplemental DRAFT Guidance: Allowable Costs for Data Management and Sharing, and

III. Supplemental DRAFT Guidance: Elements of An NIH Data Management and Sharing Plan.

Submitting a Response

Comments should be submitted electronically to the following web page: *https://osp.od.nih.gov/draft-data-sharing-and-management* by January 10, 2020. Unedited comments will be compiled and may be posted, along with the submitter's name and affiliation, on the NIH Office of Science Policy website after the public comment period closes. Submitted comments are considered public information. Please do not include any proprietary, classified, confidential, or sensitive information in your response.

DRAFT NIH Policy for Data Management and Sharing

I. Purpose

The NIH Policy for Data Management and Sharing (herein referred to as the Policy) reinforces NIH's longstanding commitment to making the results and outputs of the research that it funds and conducts available to the public. Data sharing enables researchers to rigorously test the validity of research findings, strengthen analyses through combined datasets, reuse hard-to-generate data, and explore new frontiers of discovery. In addition, NIH emphasizes the importance of good data management practices, which provide the foundation for effective data sharing and improve the reproducibility and reliability of research findings. NIH encourages data management and data sharing practices consistent with the NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research and the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles.

To promote effective and efficient data management and data sharing, NIH expects researchers to manage scientific data resulting from NIH-funded or conducted research and prospectively plan for which scientific data will be preserved and shared. Under this Policy, individuals and entities would be required to provide a Data Management and Sharing Plan (Plan) describing how scientific data will be managed, including when and where the scientific data will be preserved and shared, prior to initiating the research study. Shared data should be made accessible in a timely manner for use by the research community and the broader public. This Policy is intended to establish expectations for Data Management and Sharing Plans upon which other NIH Institutes, Centers and Offices (ICO) may supplement as appropriate.

II. Definitions

For the purposes of this Policy, terms are defined as follows:

- *Data Management and Sharing Plan (Plan):* A plan describing how scientific data will be managed, preserved, and shared with others (*e.g.,* researchers, institutions, the broader public), as appropriate.
- *Data Management:* The process of validating, organizing, securing, maintaining, and processing scientific data, and of determining which scientific data to preserve.
- *Data Sharing:* The act of making scientific data available for use by others (*e.g.,* researchers, institutions, the broader public).
- *Metadata:* Data describing scientific data that provide additional information to make such scientific data more understandable (*e.g.,* date, independent sample and variable description, outcome measures, and any intermediate, descriptive, or phenotypic observational variables).
- *Scientific Data:* The recorded factual material commonly accepted in the scientific community as necessary to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data *do not include* laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens. NIH expects that reasonable efforts will be made to digitize all scientific data.

III. Scope

This Policy applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants, contracts, intramural research projects, or other funding agreements regardless of NIH funding level or funding mechanism.

IV. Effective Date(s)

The effective date of this Policy and subsequent implementation deadlines are dependent upon feedback on this proposal. This Policy is proposed to be effective for NIH-funded or conducted research, including:

- Competing grant applications that are submitted to NIH for a future receipt date or subsequent receipt dates (date yet to be determined);
- Proposals for contracts that are submitted to NIH on or after a future date (date yet to be determined);
- NIH Intramural research conducted on or after a future date (date yet to be determined); and
- Other funding agreements (*e.g.,* Other Transactions) that are executed on or after a future date (date yet to be determined), unless otherwise stipulated by NIH.

V. Requirements

This Policy would require:

- Submission of a Data Management and Sharing Plan (Plan) outlining how scientific data will be managed and shared, taking into account any potential restrictions or limitations.
- Compliance with the NIH ICO-approved Plan, prospectively describing effective management and timely sharing of scientific data (as appropriate) and accompanying metadata resulting from NIH-funded or conducted research.

The funding NIH ICO may request additional or specific information to be included within the Plan in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research. Costs associated with data management and data sharing may be allowable under the budget for the proposed project (see below, Supplemental DRAFT Guidance: Allowable Costs for Data Management and Sharing).

VI. Data Management and Sharing Plans

Researchers with NIH-funded or conducted research projects resulting in the generation of scientific data are required to submit a Plan to the funding NIH ICO as part of Just-in-Time for extramural awards, as part of the technical evaluation for contracts, as part of the NIH Intramural Annual Report, or prior to release of funds for other funding agreements. Plans should explain how scientific data generated by a research study will be managed and which of these scientific data will be shared. Plans may be updated by researchers (with appropriate NIH ICO approval) during regular reporting intervals if changes are necessary or at the request of the NIH ICO to reflect changes in the previously documented approach to data management and data sharing throughout the research project, as appropriate. NIH encourages shared scientific data to be made available as long as it is deemed useful to the

research community or the public. Plans should also identify strategies or approaches to ensure data security and compliance with privacy protections are in place throughout the life of the scientific data. NIH may make Plans publicly available.

NIH prioritizes the responsible management and sharing of scientific data derived from human participants. Applicable Federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies dictate how research involving human participants should be conducted and how the scientific data derived from human participants should be used. Researchers proposing to generate scientific data derived from human participants should outline in their Plans how human participants' privacy, rights, and confidentiality will be protected, *i.e.,* through de-identification or other protective measures. NIH recognizes that certain factors (*e.g.,* legal, ethical, technical) may limit the ability to preserve and share data. Plans should include consideration of these factors, when applicable, in describing the approach to data management and data sharing. NIH encourages the use of established repositories for preserving and sharing scientific data.

Plan Elements: Consider addressing specific elements outlined in DRAFT guidance (see below, Supplemental DRAFT Guidance: Elements of An NIH Data Management and Sharing Plan).

Plan Assessment: The funding NIH ICO will assess the Plan, through the following processes:

- *Extramural Awards:* Plans will undergo a programmatic assessment by NIH staff within the proposed funding NIH ICO. NIH encourages potential awardees to work with NIH staff to address any potential concerns regarding the Plan prior to submission.
- *Contracts:* Plans will be included as part of the technical evaluation performed by NIH staff.
- *Intramural Research Projects:* Plans will be assessed by the Scientific Director (or designee) or Clinical Director (or designee) of the researcher's funding NIH ICO.
- *Other funding agreements:* Plans will be assessed in the context of other funding agreement mechanisms (*e.g.,* Other Transactions).

VII. Compliance and Enforcement

During the Funding or Support Period

During the funding period, compliance with the Plan will be determined by the funding NIH ICO. Compliance with the Plan, including any Plan updates, will be reviewed during regular reporting intervals (*e.g.,* at the time of annual Research Performance Progress Reports (RPPRs)) at a minimum.

- *Extramural Awards:* The Plan will become a Term and Condition of the Notice of Award. Failure to comply with the Terms and Conditions may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions.
- *Contracts:* The Plan will become a Term and Condition of the Award, and compliance with and enforcement of the Plan will be consistent with the award and the Federal Acquisition Regulations (FAR), as applicable.
- *Intramural Research Projects:* Compliance with and enforcement of the Plan will be consistent with applicable NIH policies established by the NIH Office of Intramural Research and the applicable NIH ICO.
- *Other funding agreements:* Compliance with and enforcement of the Plan will be consistent with applicable NIH policies.

Post Funding or Support Period

After the end of the funding period, non-compliance with the NIH ICO-approved Plan may be taken into account by the funding NIH ICO for future funding decisions for the recipient institution (*e.g.,* as authorized in the NIH Grants Policy Statement, Section 8.5, Special Award Conditions, and Remedies for Noncompliance (Special Award Conditions and Enforcement Actions)).

Supplemental DRAFT Guidance: Allowable Costs for Data Management and Sharing

NIH recognizes that making data accessible and reusable for other users, while integral to the research process, may require costs above and beyond the routine costs of conducting research. To assist individuals and entities who may be subject to a future NIH Policy for Data Management and Sharing, NIH is proposing supplemental DRAFT guidance regarding potential categories of allowable NIH costs associated with data management and sharing for public comment. NIH is proposing that reasonable, allowable costs may be included in NIH budget requests when associated with:

1. *Curating data and developing supporting documentation*, include formatting data according to accepted community standards; de-identifying data; attaching metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission and storage at a selected repository for long-term preservation and access.

2. *Preserving and sharing data through established repositories*, such as data deposit fees and charges necessary for making data available and accessible. When proposing to use a repository that charges recurring fees, budgets may include costs that would be incurred for preserving and sharing data. If the Plan proposes use of multiple repositories, consider including costs associated with use of each proposed repository.

3. *Local data management considerations*, such as unique and specialized information infrastructure necessary to provide local management, preservation, and access to data, (*e.g.,* before deposit into an established repository). Budget estimates should not include infrastructure costs typically included in institutional overhead (*e.g.,* Facilities and Administrative costs), nor costs associated with the routine conduct of research. Costs associated with collecting or otherwise gaining access to research data (*e.g.,* data access fees) are considered costs of doing research and should not be included in budgets.

Supplemental DRAFT Guidance: Elements of a NIH Data Management and Sharing Plan (Plan)

To assist those who may be subject to a future NIH Policy for Data Management and Sharing, NIH is proposing supplemental DRAFT guidance regarding elements of a Data Management and Sharing Plan (Plan) for public comment. A Plan should describe in two pages or less the proposed approach to data management and sharing that the specific research will employ. If certain elements of a Plan have not been determined at the time of submission, an entry of ''to be determined'' may be acceptable if a justification is provided along with a timeline or appropriate milestone at which a determination will be made. Note, NIH does not expect researchers to share all scientific data generated in a study. Elements of a Plan should consider:

1. *Data Type:* A description of the types and estimated amount of scientific data that will result from NIH-funded or conducted research, which scientific data will be preserved and shared, and the rationale for these decisions. Descriptions may include any additional metadata, information, or documentation about the scientific data that will be made publicly available (*e.g.,* study protocols, data collection instruments). In describing the data

types to be managed, preserved, and shared, consider:

• Describing data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (*e.g.,* exome sequences of 20 to 30 gene variants from an estimated 800 cases and fMRI data from ~100 research participants). Descriptions may indicate the data modality (*e.g.,* imaging, genomic, mobile, survey), level of aggregation (*e.g.,* individual, aggregated, summarized), and/or the degree of data processing that has occurred (*i.e.,* how raw or processed the data will be).

• Providing a rationale for decisions about which scientific data are to be preserved and made available for sharing, taking into consideration scientific utility, validation of results, availability of suitable data repositories, privacy and confidentiality, cost, consistency with community practices, and data security.

• Identifying metadata, other relevant data, and any associated documentation (*e.g.,* study protocols and data collection instruments) which will be made accessible to facilitate interpretation of the scientific data.

• For scientific data derived from human participants or specimens, outlining plans for providing appropriate protections of privacy and confidentiality (*i.e.,* through de-identification or other protective measures) that are consistent with applicable federal, tribal, state, and local laws, regulations, statues, guidance, and institutional policies.

2. *Related Tools, Software and/or Code:* An indication of whether specialized tools are needed to access or manipulate shared data to support replication or reuse, and name(s) of the needed tool(s) and software. Consider specifying how needed tools can be accessed, (*i.e.,* open source and freely available, generally available for a fee in the marketplace, or available only from the research team or some other source).

3. *Standards:* An indication of what standards, if any, will be applied to the scientific data and associated metadata to be collected, including data formats, data identifiers, definitions, unique identifiers, and other data documentation. While many scientific fields have developed and adopted common data standards, others have not. In such cases, the Plan may indicate that no appropriate data standards exist for the data to be collected, preserved, and shared. Provide the name of any data standards or metadata standards proposed for use, considering:

• Use of existing, widely adopted standards for scientific data and associated metadata. Some examples include: Clinical Data Interchange Standards Consortium, Minimum Information About a Microarray Experiment, Minimum Information about a high-throughput SEQuencing Experiment, and the Office of the National Coordinator for Health Information Technology Interoperability Standards Advisory.

• Use of common data elements (CDEs) to facilitate broader and more effective use of scientific data and to advance research across studies. For assistance in identifying NIH-supported CDEs, the NIH has established a Common Data Element (CDE) Resource Portal.

4. *Data Preservation, Access, and Associated Timelines:* An indication of the timelines for data preservation and access, considering:

• Where scientific data will be archived to ensure long-term preservation (*i.e.,* which repository(ies)). If scientific data will be archived in an existing data repository(ies), consider providing the name and URL web address of the repository(ies). If an existing data repository(ies) will not be used, consider indicating why not and how scientific data will be preserved and shared.

• How the scientific data will be findable and whether a persistent unique identifier or other standard indexing tools will be used, and any provisions for maintaining the security and integrity of the scientific data (*e.g.,* encryption and backups).

• Whether additional considerations are needed to implement the Plan, (*e.g.,* whether permission needs to be sought to use a specific data repository, and from whom).

• Whether scientific data generated from humans or human biospecimens will be available through unrestricted (made publicly available to anyone) or restricted access (made available only after the requestor has received approval to use the requested scientific data). If the scientific data will be shared through a restricted access mechanism, consider describing the general terms of access for the data.

• Anticipated timeframes for preserving scientific data, describing if different timelines will apply to different subsets of scientific data, and when the scientific data will be submitted to specified data repositories.

• When the scientific data will be made available to other users (*e.g.,* researchers and the broader public). In general, scientific data should be made available as soon as practicable, independent of award period and publication schedule. If applicable, consider indicating when scientific data will no longer be available to other users.

5. *Data Sharing Agreements, Licenses, and Other Use Limitations:* NIH encourages the broadest use of scientific data resulting from NIH-funded or conducted research, consistent with privacy, security, informed consent, and proprietary issues. In describing proposed plans for managing data sharing agreements and other types of arrangements, consider indicating:

• A description of any restrictions imposed by existing agreements that would limit the ability to broadly share scientific data, as well as a summarizing what those limitations on sharing or reuse are.

• Whether the applicant anticipates entering into any agreements that could limit the ability to broadly share scientific data and describe those agreements.

• Any other considerations that may result in limitations on the ability to broadly share scientific data.

• How relevant limitations to sharing are consistent with community expectations, and how scientific data will be shared to the maximum extent possible while honoring these limitations.

6. *Oversight of Data Management:* An indication of the individual(s) who will be responsible for executing various components (*e.g.,* data collection, data analysis, data submission) of the Plan over the course of the research project and the roles of the individual(s) in data management, and a description of the appropriate expertise for oversight.

Dated: October 30, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–24529 Filed 11–6–19; 4:15 pm]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more

information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

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

Proposed Project: SAMHSA's Publications and Digital Products Website Registration Survey (OMB No. 0930–0313)—Reinstatement

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for a reinstatement of SAMHSA's Publications and Digital Products website Registration Survey, formerly under the Registration for Behavioral Health website and Resources (OMB No. 0930–0313). SAMHSA is authorized under section 501(d)(16) of the Public Health Service Act (42 U.S.C. 290aa(d)(16)) to develop and distribute materials for the prevention, treatment, and recovery from mental and substance use disorders. To improve customer service and lessen the burden on the public to locate and obtain these materials, SAMHSA has developed a website that includes more than 500 free publications from SAMHSA and its component Agencies. These products are available to the public for ordering and download. When a member of the public chooses to order hard-copy publications, it is necessary for SAMHSA to collect certain customer information in order to fulfill the request. To further lessen the burden on the public and provide the level of customer service that the public has come to expect from product websites, SAMHSA has developed a voluntary registration process for its publication website that allows customers to create accounts. Through these accounts, SAMHSA customers are able to access their order histories and save their shipping addresses. During the website registration process, SAMHSA will also ask customers to provide optional demographic information that helps SAMHSA to evaluate the use and distribution of its publications and improve services to the public.

SAMHSA is employing a web-based form for information collection to avoid duplication and unnecessary burden on customers who register for an account. Customer information is submitted electronically via web forms on the samhsa.gov domain. Customers can submit the web forms at their leisure, or call SAMHSA's toll-free Call Center and an information specialist will submit the forms on their behalf. The electronic collection of information reduces the burden on the respondent and streamlines the data-capturing process.

SAMHSA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Website Registration Survey	21,082	1	21,082	.033 (2 min.)	696

Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, Maryland 20857, *OR* email a copy to *summer.king@samhsa.hhs.gov.* Written comments should be received by January 7, 2020.

Summer King,

Statistician.

[FR Doc. 2019–24382 Filed 11–7–19; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2019–0022; OMB No. 1660–0134

Agency Information Collection Activities: Proposed Collection; Comment Request; Preparedness Activity Registration and Feedback

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning FEMA's Individual and Community Preparedness Division's (ICPD) efforts to enable individuals, organizations, or other groups to register with FEMA and to take part in FEMA's preparedness mission by connecting with individuals, organizations, and communities with research and tools to build and sustain capabilities to prepare for any disaster or emergency.

DATES: Comments must be submitted on or before January 7, 2020.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2019–0022. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Christi Collins, AICP, Branch Chief, Preparedness Behavior Change, Individual and Community Preparedness Division, National Preparedness Directorate, FEMA, DHS, 400 C Street SW, Washington, DC 20024, 202.615.9865.

Christi.collins@fema.dhs.gov. You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: As part of 6 U.S.C. Sec. 313 and 314, and the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Section 611 (42 U.S.C. 5196), the mission of the Federal Emergency Management Agency (FEMA) is to reduce the loss of life and property and protect the Nation from all hazards by leading and supporting the Nation in a risk-based, comprehensive emergency management system of preparedness, protection, response, recovery, and mitigation. FEMA's Individual and Community Preparedness Division (ICPD) supports the FEMA Mission by connecting individuals, organizations, and communities with research and tools to build and sustain capabilities to prepare for any disaster or emergency. The Division conducts research to better understand effective preparedness actions and ways to motivate the public to take those actions. ICPD develops and shares preparedness resources and coordinates comprehensive disaster preparedness initiatives that empower communities to prepare for, protect against, respond to, and recover from a disaster. This mission is achieved through close coordination with the FEMA Regions and working relationships with Federal, State, local, and Tribal agencies. This includes working with nongovernmental partners from all sectors both nationally through neighborhood-based community groups.

Collection of Information

Title: Preparedness Activity Registration and Feedback.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0134 (and moving a survey from Generic Clearance, 1660–0130).

FEMA Forms: FEMA Form 008–0–8 (Preparedness Activity Registration) and FEMA Form 519–0–11 (Preparedness Activity Feedback Form).

Abstract: This collection will allow ICPD to gather the following information from the public via web form(s):

- *Feedback:* General feedback on the effectiveness of national FEMA preparedness programs and initiatives and website user experience
- *Activity Details:* Information regarding the type, size and location of preparedness activities hosted by members of the public and community organizers
- *POC Information:* For registration within the site and follow-on communication, if needed
- *Future Engagement Requests:* Allow for the public to enroll in the ICPD newsletter or other public communications
- *Publication Ordering:* Submitting requests to the FEMA publication warehouse to have materials shipped directly to members of the public

To fulfill its mission FEMA's Individual and Community Preparedness Division (ICPD) collects information from individuals and organizations by the Preparedness Activity Registration Form and the Preparedness Activity Feedback Form located within a public website (called the ''Preparedness Portal''). This collection facilitates FEMA's ability to assess its progress for the following programs:

- Ready 2 Help (*www.ready.gov/game*)
- You Are the Help Until Help Arrives (*www.ready.gov/until-help-arrives*)
- Event Registration (*www.ready.gov/prepare*) (includes Prepareathon event registration)
- Collections where ICPD partners with other National Preparedness Directorate (NPD) offices

As new programs or initiatives are created, ICPD will leverage the pre-approved questions in the question bank provided for this collection. Known future activities include:

- Community-Based Organization Continuity and Resilience Training
- website User Experience Feedback

ICPD uses this information to inform the continuous improvement of the programs and the Division's outreach. Further, the information allows the Division to analyze seasonal trends in preparedness across the variety of programs. Raw data is not shared outside of the database; only results of the data assessment is shared. The data is used for internal reports as well as public-facing talking points.

Affected Public: Individuals, organizations and groups who wish to register for ICPD Preparedness activities to take advantage of FEMA's related resources and available supporting materials.

Estimated Number of Respondents: 86,115.

Estimated Number of Responses: 86,115.

Estimated Total Annual Burden Hours: 7,174.

Estimated Total Annual Respondent Cost: $196,424.

Estimated Respondents' Operation and Maintenance Costs: There are no operation and maintenance costs for respondents.

Estimated Respondents' Capital and Start-Up Costs: There are no capital and start-up costs for respondents.

Estimated Total Annual Cost to the Federal Government: $12,205.

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,

Deputy Director of Information Management, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2019–24372 Filed 11–7–19; 8:45 am]

BILLING CODE 9111–27–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7016–N–04]

60-Day Notice of Proposed Information Collection: Survey of Market Absorption of New Multifamily Units

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The U.S. Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 7, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5534 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Survey of Market Absorption of New Multifamily Units.

OMB Approval Number: 2528–0013 (Expires July 31, 2020).

Type of Request (*i.e.,* new, revision or extension of currently approved collection): Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Survey of Market Absorption (SOMA) provides the data necessary to measure the rate at which new rental apartments and new condominium apartments are absorbed; that is, taken off the market, usually by being rented or sold, over the course of the first twelve months following completion of a building. The data are collected at quarterly intervals until the twelve months conclude, or until the units in a building are completely absorbed. The survey also provides estimates of certain characteristics, including asking rent/price, number of units, and number of bedrooms. The survey provides a basis for analyzing the degree to which new apartment construction is meeting the present and future needs of the public.

Members of affected public: Rental Agents/Builders.

Estimated Number of Respondents: 12,000 yearly (maximum).

Estimated Time per Response: 15 minutes/initial interview and 5 minutes for any subsequent interviews (up to three additional, if necessary).

Frequency of Response: Four times (maximum).

Estimated Total Annual Burden Hours: 6,000 (12,000 buildings × 30 minutes).

Estimated Total Annual Cost: The only cost to respondents is that of their time. The total estimated cost to HUD in FY 2020 is $1,830,000.

Respondent's Obligation: Voluntary.

Legal Authority: The survey is conducted under Title 12, United States Code, Section 1701Z.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
SOMA	12,000	4	48,000	.125 (30 minutes total divided by 4 interviews).	6,000	$0	$0
Total	12,000	4	48,000	.125	6,000	0	0

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 28, 2019.

Seth D. Appleton,

Assistant Secretary for Policy Development and Research.

[FR Doc. 2019–24433 Filed 11–7–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–49]

30-Day Notice of Proposed Information Collection: Moving to Work Amendment to Consolidated Annual Contributions Contract (ACC)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the information collection described below to the Office of Management and Budget (OMB) for review and approval, in accordance with the Paperwork Reduction Act. HUD has revised the *Moving to Work Amendment to the Consolidated Annual Contributions Contract (ACC)* (''MTW ACC Amendment'') in response to public comments received during the public comment period provided for by the 60-Day Notice of Proposed Information Collection. These revisions are more thoroughly described below. This publication is to provide notice to PHAs of the revisions and to give PHAs the opportunity to comment on such revisions. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* December 9, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to

the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806; email: *OIRA_Submission@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 27, 2018 at 83 FR 66738.

A. Background

In order to implement the expanded MTW program under division L, title II of the Consolidated Appropriations Act, 2016 (Pub. L.114–113, December 18, 2015), HUD issued the first Operations Notice of the Expansion of the Moving to Work Demonstration Program Solicitation of Comment (82 FR 8056, January 23, 2017) (Operations Notice), and solicited public comment. This notice established requirements for the implementation and continued operation of the expansion of the MTW demonstration program pursuant to the 2016 MTW Expansion Statute and certain pre-approved waivers to establish program flexibility for participants. These waivers will be available to MTW PHAs when the revised MTW ACC Amendment is executed. The Operations Notice also provided that the 100 PHAs would be selected in cohorts, with applications for each cohort to be sought via a Selection Notice.

This initial Operations Notice was followed by subsequent **Federal Register** notices. On May 4, 2017, HUD published the Operations Notice for the Expansion of the Moving to Work Demonstration Program Solicitation of Comment; Waiver Revision and Reopening of Comment Period.'' On October 5, 2018, HUD published a further Operations Notice (83 FR 50387)(a correction and extension of the comment period was published on October 11, 2018 (83 FR 51474)). This notice made changes as a result of the prior public comments, and again solicited public comments. HUD plans to issue the final MTW Operations Notice separately.

On December 27, 2018, HUD issued for public comment the 60-day notice for the Moving to Work Amendment to the Consolidated Annual Contributions Contract (the ''MTW ACC Amendment'') under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (83 FR 66738). The MTW ACC Amendment has been revised in response to public comments received under the 60-day Notice. The formal title has also been changed to the ''Moving to Work Amendment to the Annual Contributions Contract(s).'' The revised MTW ACC Amendment will govern the 100 new PHAs' participation in the MTW demonstration pursuant to the 2016 legislation. It will allow the PHAs to exercise the flexibilities provided by the MTW Operations Notice and their respective Selection Notice and require compliance with the terms and conditions of each Notice respectively. This notice follows the 60-day notice.

B. Overview of Information Collection

Title of Information Collection: Moving to Work Amendment to Consolidated Annual Contributions Contract.

OMB Approval Number: Pending OMB approval.

Type of Request: New collection.

Form Number: HUD–50166.

Description of the need for the information and proposed use: The proposed Moving to Work (MTW) Amendment to the Annual Contributions Contract(s), signed by HUD and the selected Public Housing Authority (PHA), is necessary for HUD to implement the expansion of the Moving to Work program enacted by Congress in the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, approved December 18, 2015) (2016 Appropriation). It establishes the basic terms and conditions that will apply to 100 new PHAs participating in the MTW demonstration pursuant to the 2016 Appropriation. Specifically, the MTW ACC Amendment amends any ACCs for the public housing or housing choice voucher programs in effect between the PHA and HUD to establish the PHA's designation as an MTW agency and to operate in accordance with the requirements of the MTW demonstration program, as amended by Public Law 114–113. The MTW ACC Amendment establishes the terms of participation in MTW, including the requirement that the PHA follow the MTW Operations Notice and its respective Selection Notice. The PHAs remain subject to the applicable ACCs when the provisions are not otherwise waived by the Operations Notice or the applicable MTW Selection Notice. Additionally, the MTW ACC Amendment outlines PHA transition out of the demonstration and HUD termination rights upon PHA default. A copy of the proposed MTW ACC Amendment is published at the end of this notice. Please note that the 30-Day Notice of Proposed Information Collection for the *Public Housing Annual Contributions Contract for Capital and Operating Grant Funds (Public Housing ACC)* is published elsewhere in this issue of the **Federal Register**.

This 30-Day Notice of Proposed Information Collection provides PHAs with notice of revisions to the proposed MTW ACC Amendment published on December 27, 2018 in the 60-Day Notice of Proposed Information Collection at 83 FR 66738. The MTW ACC Amendment published in this notice revises several provisions published in the 60-Day Notice in response to public comments received. These revisions are summarized in Section E of this notice. Additionally, HUD has summarized public comments and provided responses to those comments in Section F of this notice.

Respondents: Public housing agencies.

Total Estimated Burdens: The burden costs associated with this collection are as follows:

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
HUD–50166 MTW ACC Amendment.	100	1 each	1	1.00	100	$52.88	$5,288

The burden costs shown represent burden associated with a *one-time* execution of the MTW ACC Amendment for each of 100 PHAs to be designated as MTW pursuant to the FY2016 Appropriations Statute. Previously, in the 60-Day PRA Notice published on December 27, 2018, HUD under-estimated the estimated burden hours associated with the execution of the MTW ACC Amendment. The burden hours did not account for the review time associated with the one-time execution of the MTW ACC Amendment.

C. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

D. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

E. Overview of Significant Changes Made to the MTW ACC Amendment

The following represents the most notable changes to the MTW ACC Amendment. However, other changes have also been made which may not be identified below because they are editorial or non-material and minor changes. The MTW ACC Amendment should be reviewed in its entirety to determine the exact nature and scope of these revisions. A copy of the revised MTW ACC Amendment is published at the end of this notice.

- HUD changed the title of the document from the Moving to Work Amendment to the Consolidated Annual Contributions Contract(s) (MTW CACC Amendment) to the Moving to Work Annual Contributions Contract(s) (MTW ACC Amendment) in conjunction with changes made to the Public Housing ACC. The document continues to amend any ACC in effect between the PHA and HUD for the public housing or housing choice voucher programs (including the ''Consolidated Annual Contributions Contract for the Rental Certificate and Rental Voucher programs'').
- HUD amended Section 4 of the amendment and extended the term of this amendment from 12 to 20 years, and to clarify that the effective date of the amendment is at the start of the first full PHA fiscal year after execution of the amendment by the PHA and HUD.
- HUD deleted Section 10 of the amendment as a result of the changes to Section 4, which rendered it superfluous.
- HUD amended Section 5(C) of the Amendment to clarify that exemptions from statutory and regulatory requirements pursuant to the MTW Operations Notice extend to the implementing subregulatory requirements in response to public comments.
- HUD amended Section 6 of the Amendment in response to public comments to clarify that a transition plan is not needed a year prior to termination of the MTW ACC Amendment if the PHA's participation in the MTW demonstration program is extended in advance of the final year of the term of the MTW ACC Amendment. HUD also made changes to this section to clarify submission and approval process for the transition plan and to clarify that a subsequent amendment to the ACC may be needed to allow continuation of MTW authority necessary to continue some activities under the transition plan after the term of the amendment.
- HUD amended Section 7(B) of the Amendment in response to public comments to remove remedies related to suspending, reducing, or offsetting funding, which are covered by the ACC.
- HUD amended Section 8 of the Amendment for clarity.
- HUD added a severability clause in Section 9 to ensure that the Amendment remains in effect allowing for the continued administration of the MTW demonstration program in the event of litigation affecting one of the Amendment provisions.

F. Summary of MTW ACC Amendment Comments and HUD Responses

Comment: Commenters felt that the Standard MTW Agreement was necessary to ensure that new MTW agencies would be part of the same program as the existing 39 MTW PHAs, consistent with the intent of Congress in expanding the MTW demonstration program.

HUD Response: A fundamental goal of the MTW expansion is to provide MTW expansion PHAs with many of the same flexibilities that the existing agencies have. For that reason, the framework of the MTW expansion was drafted with the intent to provide generally the same flexibilities of the existing MTW agencies (after consideration of the legal authority provided by the MTW statute and continued necessity given changes in law and regulations) in a framework that is simplified for both HUD and MTW PHAs and ensures resident protections. Through the MTW Operations Notice, HUD is creating a simpler and streamlined structure for new MTW PHAs and for HUD. The MTW Operations Notice makes it clear what statutory or regulatory provisions the authorization is waiving and what activities can be implemented without further HUD approval. This is important for scalability, monitoring, and allowing the same flexibilities with simplified administrative oversight. Further, in the event a 1937 Act statutory or regulatory provision is not included within the MTW Operations Notice, an MTW expansion agency may use its MTW authority to request to waive the statute or regulation, as long as it does not conflict with a cohort study or is not one of the statutory provisions restricted by Congress.

Additionally, operating the demonstration program via the MTW Operations Notice, effectuated for each agency via execution of the MTW ACC Amendment, rather than by using individual MTW Agreements allows for consistency of interpretation and administration of provisions such as the MTW funding formula (rather than having various individual formulae), avoiding the potential for misinterpretations and inconsistent treatment among PHAs. The MTW ACC amendment is necessary to allow the agency to exercise the flexibilities provided by the MTW Operations Notice and to require compliance with the terms thereof. This programmatic structure is essential for scalability of the MTW demonstration program; administration of over 100 individual MTW Agreements is not feasible for HUD.

Comment: Commenters expressed concerns, that unlike an MTW agreement, the MTW Operations Notice implemented through the MTW ACC Amendment could be unilaterally changed by HUD. Commenters also stated that substantive changes to the Notice affecting the terms of an MTW agency's participation in the

demonstration should be subject to notice and comment procedures.

HUD Response: To improve scalability and allow for ease of adding additional flexibilities to the demonstration, PIH looked to the Rental Assistance Demonstration (RAD) program and its implementation through HUD notices. Using RAD's model, HUD will be able to revise the MTW Operations Notice as it learns from and develops the demonstration, whereas it is much more difficult to amend over 100 contracts. The MTW Operations Notice states that any significant updates to the Operations Notice by HUD will be preceded by a public comment period.

Comment: Commenters were concerned about HUD's ability to discontinue an agency's activity and felt that the reasons for which HUD would do this were unclear.

HUD Response: Language about discontinuation of activities has been removed from the MTW ACC Amendment in response to public comments. The final MTW Operations Notice will provide additional information on the factors HUD will evaluate when considering requiring a PHA to discontinue an activity.

Comment: Commenters expressed concern that the language making the PHA subject to all HUD requirements other than those statutory and regulatory provisions waived pursuant to the MTW Operations Notice would void all MTW flexibilities because of the potential for conflicting requirements in subregulatory guidance.

HUD Response: HUD has added language to clarify that exemptions from statutory and regulatory requirements pursuant to the MTW Operations Notice extend to subregulatory guidance to the extent that that subregulatory guidance implements statutory and regulatory requirements waived by the MTW Operations Notice in response to these concerns.

Comment: Commenters expressed concern over the mechanisms surrounding the end of the 12-year term of participation and an MTW PHA's ability to retain waivers to continue successful activities.

HUD Response: HUD has amended Section 6 of the ACC to acknowledge that, in the event of an ACC amendment extension, the transition plan would not be due at the end of the initial term but at the end of the extension(s). HUD has also clarified the process by which an agency can request continued use of certain MTW flexibilities if/when its term of participation expires. HUD also extended the term of participation to 20 years in Section 4.

Comment: Some commenters felt that the termination and default remedies authorized to HUD were excessive and redundant of remedies provided by the ACC.

HUD Response: HUD has removed remedies related to suspending, reducing, or offsetting funding, in Section 7, as this language is covered in the ACC(s).

Comment: Some commenters stated that language in the MTW ACC Amendment appeared to reflect an attempt by HUD to protect itself from future lawsuits similar to ones it has lost with existing MTW agencies.

HUD Response: As HUD has stated in the responses to comments on the Public Housing ACC published elsewhere in this issue, these changes were not proposed in response to litigation, but HUD is aware of litigation surrounding the ACC. HUD makes clear in the current version of the ACC that HUD has never contemplated money damages for action or inaction by HUD with respect to the ACC. This is also true of the MTW ACC Amendment. Nothing in the revised ACC or MTW ACC Amendment forecloses avenues for judicial relief from any HUD action that is arbitrary, capricious or contrary to law.

Comment: Some commenters objected to issuance of the MTW ACC Amendment through the Paperwork Reduction Act (''PRA'') rather than the notice and comment rulemaking process required by the Administrative Procedures Act (the ''APA''). Commenters stated that the PRA standards for public comments do not satisfy APA requirements.

HUD response: The MTW ACC Amendment is an information collection under the definitions in 5 CFR 1320.3(c)(1), which states that a collection of information may be in any form or format, including a contract or an agreement. The ACC is a form with an OMB form number, therefore, review and public comment under the PRA are appropriate.

Contrary to statements made by commenters, the PRA process does require solicitation of and response to public comments (see 5 CFR 1320.5(a)(1)(iii)(F) (requiring ''A summary of the public comments received under § 1320.8(d), including actions taken by the agency in response to the comments''). HUD received public comments from several public housing industry groups and existing MTW agencies and is responding to the issues raised with this notice.

Dated: November 5, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

Moving to Work Amendment to Annual Contributions Contract(s)

Section 1. This Moving to Work (MTW) Amendment to the Annual Contributions Contract(s) (MTW ACC Amendment) is entered into between the United States Department of Housing and Urban Development (''HUD'') and _____ (the ''Public Housing Agency, ''PHA'').

Section 2. This MTW ACC Amendment is an amendment to any Annual Contributions Contract (''ACC'') or Annual Contributions Terms and Conditions (''ACC'') in effect between the PHA and HUD for the Public Housing and Housing Choice Voucher programs.

Section 3. The ACC is amended in connection with the PHA's designation as a participant in the expansion of the MTW demonstration pursuant to Section 239 of the Consolidated Appropriations Act, 2016, Public Law 114–113; 129 Stat. 2897 (2016 MTW Expansion Statute) and Section 204 of the Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act, 1996, Public Law 104–134; 110 Stat. 1321–281 (1996 MTW statute). The PHA's participation in the expansion of the MTW demonstration shall be governed by the MTW Operations Notice for the Expansion of the Moving to Work Demonstration as it is issued and may be amended in the future, or any successor notice issued by HUD, (''the MTW Operations Notice'').

Section 4. The term of this amendment shall be for 20 years from the beginning of the PHA's first full fiscal year following execution by the PHA and HUD; or, until termination of this amendment, whichever is sooner.

Section 5. Requirements and Covenants.

(A) As a participant in the MTW demonstration, the PHA must operate in accordance with the express terms and conditions set forth in the MTW Operations Notice. The MTW Operations Notice may be superseded or amended by HUD at any time during the twenty-year MTW term.

(B) The PHA will cooperate fully with HUD and its contractors for the duration of the HUD-sponsored evaluation of the cohort of the MTW Expansion for which the PHA was selected and shall comply with all aspects of its Cohort Study as outlined in the selection notice under which the PHA was designated.

(C) The PHA is exempted from specific provisions of the Housing Act of 1937 (''the Act'') and its implementing regulations as specified in the Operations Notice. Each such exemption also extends to subregulatory guidance to the extent that the subregulatory guidance implements the provisions of the Act or its implementing regulations exempted pursuant to the Operations Notice. Notwithstanding any exemptions pursuant to this MTW ACC amendment and the MTW Operations Notice, the PHA remains subject to all other HUD Requirements (which include the Public Housing Requirements), as they may be amended in the future. Accordingly, if any HUD Requirement, other than the exempted provisions of the Act and its implementing regulatory requirements or subregulatory guidance, conflicts with any authorization granted by this MTW ACC Amendment, the MTW Agency remains subject to that HUD Requirement.

Section 6. At least one year prior to expiration of this MTW ACC Amendment,[1] the PHA shall submit a transition plan to HUD. It is the PHA's responsibility to be able to end all MTW activities that it has implemented through its MTW Supplement to the PHA Plan upon expiration of this MTW ACC Amendment. The transition plan shall describe plans for phasing out such activities. The plan may also include any proposals of authorizations/features of the ACC Amendment and the MTW Operations Notice that the PHA wishes to continue beyond the expiration of the MTW ACC Amendment. The PHA shall specify the proposed duration and shall provide justification for extension of such authorization/features. HUD will review and respond to timely-submitted transition plans from the PHA in writing within 75-days or they are deemed approved. Only authorizations/features specifically approved for extension shall continue beyond the term of the MTW ACC Amendment. The extended features shall remain in effect only for the duration and in the manner specified in the approved transition plan and be subject to any necessary ACC Amendments as required by HUD.

Section 7. Termination and Default.

(A) If the PHA violates or fails to comply with any requirement or provision of the ACC, including this amendment, HUD is authorized to take any corrective or remedial action described in this Section 7 for PHA default or any other right or remedy existing under applicable law, or available at equity. HUD will give the PHA written notice of any default, which shall identify with specificity the measures, which the PHA must take to cure the default and provide a specific time frame for the PHA to cure the default, taking into consideration the nature of the default. The PHA will have the opportunity to cure such default within the specified period after the date of said notice, or to demonstrate within 10 days after the date of said notice, by submitting substantial evidence satisfactory to HUD, that it is not in default. However, in cases involving clear and apparent fraud, serious criminal behavior, or emergency conditions that pose an imminent threat to life, health, or safety, if HUD, in its sole discretion, determines that immediate action is necessary it may institute the remedies under Section 7(B) of this MTW ACC Amendment without giving the PHA the opportunity to cure.

(B) If the PHA is in default of this MTW ACC Amendment and/or the MTW Operations Notice and the default has not been cured, HUD may, undertake any one or all remedies available by law, including but not limited to the following:

i. Require additional reporting by the PHA on the deficient areas and the steps being taken to address the deficiencies;

ii. Require the PHA to prepare and follow a HUD-approved schedule of actions and/or a management plan for properly completing the activities approved under this MTW ACC Amendment;

iii. Suspend the MTW waiver authorization for the affected activities;

iv. Require reimbursement by the PHA to HUD for amounts used in violation of this MTW ACC Amendment;

v. Terminate this MTW ACC Amendment and require the PHA to transition out of MTW;

vi. Restrict a PHA's ability to use its MTW funding flexibly; and/or

vii. Take any other corrective or remedial action legally available.

(C) The PHA may choose to terminate this MTW ACC Amendment at any time. Upon HUD's receipt of written notification from the PHA and a copy of a resolution approving termination from its governing board, termination will be effective. The PHA will then begin to transition out of MTW and will work with HUD to establish an orderly phase-out of MTW activities, consistent with Section 6 of this MTW ACC Amendment.

(D) Nothing contained in this ACC amendment shall prohibit or limit HUD from the exercise of any other right or remedy existing under any ACC or available under applicable law. HUD's exercise or non-exercise of any right or remedy under this amendment shall not be construed as a waiver of HUD's right to exercise that or any other right or remedy at any time.

Section 8. Notwithstanding any provision set forth in this MTW ACC Amendment, any future law that conflicts with any provision of this ACC Amendment, as determined by HUD, shall not be deemed to be a breach of this ACC Amendment. Nor shall HUD's execution of any future law be deemed a breach of this ACC Amendment. Any future laws affecting the PHA's funding, even if that future law causes a decrease in the PHA's funding, shall not be deemed a breach of this ACC Amendment. No future law or HUD's execution thereof shall serve as a basis for a breach of contract claim in any court.

Section 9. If any clause, or portion of a clause, in this Agreement is considered invalid under the rule of law, it shall be regarded as stricken while the remainder of this Agreement shall continue to be in full effect.

In consideration of the foregoing covenants, the parties do hereby execute this MTW ACC Amendment:

PHA

_____

By: _____

Its: _____

Date: _____

UNITED STATES DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

_____

By: _____

Its: _____

Date: _____

[FR Doc. 2019–24473 Filed 11–7–19; 8:45 am]

BILLING CODE 4210–67–P

[1] Should the PHA receive an extension(s) of its MTW participation (*e.g.* by extension or replacement of its MTW ACC Amendment) the transition plan will be due one year prior to the end of the extension(s).

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–50]

30-Day Notice of Proposed Information Collection: Public Housing Annual Contributions Contract for Capital and Operating Grant Funds: 30-Day Notice of Proposed Information Collection: Agency Information Collection Activities: Public Housing Annual Contributions Contract for Capital and Operating Grant Funds

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the information collection described below to the Office of Management and Budget (OMB) for review and approval, in accordance with the Paperwork Reduction Act. The public housing program provides Operating Funds and Capital Funds to public housing projects owned and operated by public housing agencies (PHAs), subject to the terms and conditions contained in the federal award, HUD–53012.

HUD has revised the federal award based on current applicable statutes and regulations as well as in response to public comments received during the public comment period provided for by the 60-Day Notice of Proposed Information Collection. These revisions are more thoroughly described below. One notable revision is that HUD has revised the title of the public housing federal award; previously entitled *Public Housing Annual Contributions Contract for Capital and Operating Grant Funds,* the award will now be entitled *Annual Contributions Terms and Conditions for the Public Housing Program.* For clarity and consistency, the award will continue to be referred to as ''ACC.'' Additionally, mixed-finance provisions in the proposed ACC have been removed from the revised ACC and will instead be included in an ACC amendment; a model mixed-finance ACC amendment is published herewith.

This publication is to provide notice to PHAs of the revisions and to give PHAs the opportunity to comment on such revisions. The purpose of this notice is to allow for an additional 30 days of public comment. Please note that the 30-Day Notice of Proposed Information Collection for the Moving to Work Amendment to Consolidated Annual Contributions Contract is published elsewhere in this issue of the **Federal Register**.

DATES: *Comments Due Date:* December 9, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Officer of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806; email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 27, 2018 at 83 FR 66729.

A. Overview of Information Collection

Title of Information Collection: Annual Contributions Terms and Conditions for the Public Housing Program.[1]

OMB Approval Number: 2577–0075.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–53012.[2]

Description of the need for the information and proposed use: The proposed *Annual Contributions Terms and Conditions for the Public Housing Program (ACC)* is necessary to establish the basic terms and conditions for a PHA's public housing program and requires the PHA to manage and operate its public housing projects in accordance with the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*) (1937 Act) and all applicable HUD requirements.

This 30-Day Notice of Proposed Information Collection provides PHAs with notice of revisions to the current ACC form HUD–53012. The ACC published in this notice updates HUD–53012 to streamline the ACC. In order to further streamline the ACC and in response to public comments received, the ACC published in this notice deletes or revises several ACC provisions published in the 60-Day Notice of Proposed Information Collection. Those revisions are summarized in Section E of this notice. Additionally, HUD has summarized public comments and provided responses to those comments in Section F of this notice.

Respondents: Public housing agencies.

Total Estimated Burdens: The burden costs associated with this collection are as follows:

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Cost
HUD–92577 ACC	3,107	1 each	1	1.00	3,107	$52.88	$164,298
Mixed-Finance Amendment.	94	1 each	1	1.00	94	52.88	4,970

The burden costs shown represent burden associated with a *one-time* execution of the ACC for all PHAs and the burden represented with each *one-time* transactional execution of a Mixed-Finance Amendment to the ACC, with

[1] The previous title was *Public Housing Annual Contributions Contract for Capital and Operating Grant Funds.*

[2] The forms listed in the 60-Day Notice were ''HUD–52840A, HUD–53012A, HUD–53012B.'' HUD forms HUD–53012A and HUD–53012B have been combined into one form, HUD–53012. HUD is not revising HUD–52840A, the *Capital Fund Program (CFP) Amendment to the Annual Contributions Contract (ACC),* with this proposed information collection. The HUD–52840A (exp. 01/31/2021) is available at HUDCLIPS, *https://www.hud.gov/program_offices/administration/hudclips/forms.* If HUD continues to use the HUD–52840A, it will be incorporated into the ACC as an amendment. The forms approved as part as OMB Control Number 2577–0075 that are not being revised at this time are: HUD–51999; HUD–52190A; HUD–52190B; HUD–52840A; HUD–52860, HUD–52860B, HUD–52860C; HUD–52860; HUD–52860E, and HUD–52860F, HUD–52860G, HUD–5838 and HUD–5837 (expiration date of 01/31/2021).

94 such transactions estimated to occur in any given year. Previously, in the 60-Day PRA Notice published on December 27, 2018 at 83 FR 66729, HUD over-estimated the estimated burden hours associated with the execution of the ACC and the Mixed-Finance ACC Amendment. The burden hours did not account for the fact that the ACC and Mixed-Finance ACC Amendment have been streamlined and no longer repeat statutory and regulatory requirements. Additionally, the burden hours included the hours estimated for all HUD forms that are part of OMB Control Number 2577–0075, not just the ACC and the Mixed-Finance ACC Amendment. During the 60-Day comment period, HUD received no comments related to the estimated burden hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

D. Background

In 1995 the Department of Housing and Urban Development (HUD) issued PIH Notice 95–44 which transmitted Consolidated Annual Contributions Contract (ACC), Form HUD–53012A and Form HUD–53012B. The forms were intended to replace the 1969 Consolidated ACC(s) (Form HUD–53011), and any amendments to the ACC, between HUD and HAs with respect to low-rent and homeownership public and Indian housing projects. HUD noted that:

[t]he revised ACC eliminates the recitation of the specific statutory, regulatory and executive order requirements to which a HA is subject with respect to its public or Indian housing projects. Instead, the HA is made subject to ''all applicable laws, executive orders and regulations,'' whether or not these authorities are specifically incorporated by reference in the ACC. The purpose of this revision is to minimize the scope of the requirements contained in the ACC, so that this document can remain a living and vital contract even after statutes, executive orders and regulations to which a HA is subject are enacted, promulgated, amended or repealed. With the execution of this revised ACC, HUD intends to eliminate the obsolescence that has developed over time in the existing ACC as a result of the enactment of new legislation and the promulgation of new regulations that conflict with specific requirements contained in the ACC.

HUD is further revising the ACC to achieve the goals first articulated in 1995, to ''eliminate specific statutory, regulatory and executive order requirements to which a PHA is subject . . . and to minimize the scope of the requirements contained in the ACC.'' HUD's intent is to include those terms and conditions that apply to the acceptance and use of federal financial assistance for the public housing program which are necessary to ''*insure the lower income character of the project involved in a manner consistent with the public housing agency plan*'' (42 U.S.C. 1437d), and that are not already specifically included in HUD regulations at Title 24 of the Code of Federal Regulations (CFR), the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (''Uniform Guidance'' at 2 CFR part 200), and/or made applicable by statute.

HUD initially proposed a revised ACC through an information collection Paperwork Reduction Act (PRA) 60-day Notice soliciting public comment issued on March 1, 2016 at 81 FR 10651. The changes were primarily additional requirements applicable to mixed-finance and public housing development, and clarifications and updates consistent with the Uniform Guidance. HUD received no public comments on the 60-day notice. On September 6, 2017, HUD issued a 30-day notice soliciting public comment at 82 FR 42106, and no comments were received. HUD received considerable feedback on the ACC it issued. As a result, HUD decided to re-open the ACC a second time for additional public comment. On December 27, 2018 HUD published a revised ACC in the **Federal Register** via a second PRA notice at 83 FR 66729. This notice provided 60-days for the public to comment on the revised ACC. The comments received are summarized in Section F of this notice.

E. Overview of Significant Changes Made to the ACC

The following represents the most notable changes to the ACC. However, other changes have also been made which may not be identified below because they are editorial or non-material and minor changes. The ACC should be reviewed in its entirety to determine the exact nature and scope of these revisions. HUD has posted a document online that provides a side-by-side comparison of the ACC proposed in the 60-Day Notice and the ACC proposed in this 30-Day Notice. The side-by-side document is available at *https://www.hud.gov/program_offices/public_indian_housing/programs/ph/capfund/2018pi/acc.*

- The revised agreement is retitled slightly to more clearly reflect its purpose. The new title is the *Annual Contributions Terms and Conditions for the Public Housing Program.* For clarity and consistency, the agreement will continue to be referred to as ''ACC.''
- In the 1995 ACC, the PHA was made subject to ''all applicable laws, executive orders and regulations,'' whether or not these authorities are specifically incorporated by reference in the ACC. The ACC published in the 60-day notice on December 27, 2018 contained similar language in Section 3 of the ACC (HUD Requirements). The revised ACC requires the PHA to administer its Public Housing Funds in compliance with all ''Public Housing Requirements,'' which include the United States Housing Act of 1937 (1937 Act), HUD regulations at Title 24 CFR, the Uniform Guidance, appropriations acts, and ''other federal statutes, regulations and executive orders applicable to Public Housing Funds and Public Housing Projects,'' as they exist now and amended in the future, whether or not those requirements are incorporated by reference in the ACC.
- HUD deleted the following definitions: Annual Contributions Contract, Consolidated Contributions Contract, Cooperation Agreement, Fiscal Year, Grant Funding Exhibit, Operating Costs (Operating Expenditures or Operating Expenses), Operating Receipts, Operating Reserve, Program, Program Receipts, and Replacement Reserve Account.

• HUD has used the term ''public housing funds'' in a manner that defines such term in Section 1. Additionally, in Section 1, HUD has included by reference to existing regulations at Title 2 Part 200 of Code of Federal Regulations (CFR) the following terms: Federal award, federal financial assistance, and recipient; and Section 2 has included by reference to existing regulation at 24 CFR 905.108 the definition of ''public housing project.'' In Section 2, the term Public Housing Requirements is also defined. Finally, HUD has included a new Section 11—Remedies, in response to public comments.

• HUD has responded to public comments by excluding all mixed-finance specific language in the revised ACC. HUD has determined that, to the extent PHAs need mixed-finance terms that vary from what is stated in the ACC, HUD will continue to work with PHAs on project-specific solutions, including the use of the revised mixed-finance amendment (a copy of HUD's revised model document is published herewith), adding language to Regulatory and Operating Agreements that are required for mixed-finance development, or adding language to the restrictive covenant.

• HUD has deleted the following sections from the 60-day published ACC: Section 1—Definitions, Section 2—Mission of HUD and PHA, Section 4—Cooperation Agreement, Section 9—Accounts, Records and Government Access, Section 14—HUD in Possession of Project(s). Please refer to Section G of this notice to review a chart summarizing these deletions as well as the existing statutory or regulatory public housing requirements that already apply to PHAs.

• HUD has retained but revised in part the following sections from the 60-day published ACC: Section 3—HUD Requirements (retained in part at Section 2), Section 5—Declaration of Restriction Covenants (retained in part at Section 4), Section 6—Disposition and Encumbrances (retained in part at Section 3), Section 7—Insurance Requirements (retained in section 5), Section 8—Employer Requirements (retained at Section 6), Section 10—Grant Funding (revised and retained in part at Section 1), Section 11—Depository (revised and retained in part at Section 7), Section 12—Termination of a Project (revised and retained in part at Section 10), Section 13—Notices, Defaults, Remedies (retained in part at Section 9), Section 15—Conflicts of Interests (revised and retained in part at Section 8), Section 16—Civil Rights and Employment Requirements (retained in part at Section 6), Section 17—Members or Delegates to Congress (HUD has retained prohibition in Section 8), Section 18—Rights of Third Parties (retained at Section 12), and Section 19—Waiver or Amendment (revised and retained at Section 13).

F. Summary of Public Comments Responding to the 60-Day Information Collection Notice

HUD received 79 comments on the revised ACC published on December 27, 2018 through *www.regulations.gov.* The comments can be found on the *www.regulations.gov* website at *https://www.regulations.gov/docket?D=HUD-2018-0103.* HUD also received two additional letters relating to the proposed ACC outside of the formal public comment process: A letter from a public housing agency forwarded by Congressman H. Morgan Griffith and a letter from Senator Charles E. Grassley.

ACC Generally

Comment: Commenters disagreed with HUD's characterization of the ACC as a grant agreement for a variety of reasons. Commenters asked: If the new ACC is substantively the same as the old ACC, why is HUD revising it? Others felt that HUD was misinforming the public about its ACC changes when HUD stated that it was simply adding requirements applicable to mixed-finance public housing development and making minor clarifications. Finally, some commenters felt HUD's primary motivation for proposing these changes was its loss in the United States Court of Federal Claims in suits contesting the Department's funding distribution method used in 2012.

HUD Response: The changes update the ACC to reflect that the Office of Management and Budget (OMB) revised its Uniform Guidance which applies to all agencies that award federal financial assistance (with regard to the public housing program, these requirements were formerly covered in HUD regulations at 24 CFR part 85). The revised ACC ensures that the Uniform Guidance is applied consistently, and that all PHAs are subject to the same terms and conditions applicable to public housing funds.

Additionally, the changes are intended to achieve the goals first articulated in 1995 to eliminate ''the recitation of the specific statutory, regulatory and executive order requirements to which a HA is subject . . .'' (See PIH Notice 95–44 transmitting the 1995 ACC). This revision further minimizes the scope of the requirements contained in the ACC. Since 1995 there have been numerous changes to the specific statutory, regulatory and executive order requirements to which a PHA is subject with respect to its public projects. For example, on October 24, 2013 HUD revised the Capital Fund Program at 24 CFR part 905 (78 FR 63770). Part 905 combines and streamlines the former legacy public housing modernization programs, including the Comprehensive Grant Program, the Comprehensive Improvement Assistance Program and the Public Housing Development Program (which encompasses mixed-finance development).

More than 400 PHAs continue to operate under the 1969 version of the ACC, which was developed prior to the conversion of the public housing program from a loan program. In 1995, HUD noted PHAs that failed to execute the revised ACC would continue to be governed by requirements contained in their existing ACC with HUD, which in certain instances was more restrictive than requirements established in the revised 1995 ACC (*e.g.,* the revised 1995 ACC eliminated the requirement under section 307(A) of the 1969 version concerning the need for a comparability analysis of PHA personnel policies and the 1969 ACC term for PHA procurements set at two years with a one-year option with the approval of HUD).

The ACC, pursuant to section 6(a) of the 1937 Act, sets forth the terms and conditions deemed necessary by HUD to insure the low-income character of public housing projects and that PHAs act in accordance with Public Housing requirements. The ACC governs PHA conduct in connection with its acceptance and receipt of federal assistance. While addressing past litigation outcomes is not a principal purpose for HUD's revisions to the ACC, HUD makes clear in the current version that HUD has never contemplated money damages for action or inaction by HUD with respect to the ACC. Nothing in the revised ACC forecloses avenues for judicial relief from any HUD action that is arbitrary, capricious or contrary to law.

Comment: A commenter stated that PHAs are confused, anxious, and concerned as to what HUD's changes are trying to remedy.

HUD Response: The revised ACC ensures that the Uniform Guidance is applied consistently, and that all PHAs are subject to the same terms and conditions applicable to public housing funds. Additionally, the changes eliminate specific statutory, regulatory and executive order requirements to which a PHA is subject and to minimize the scope of the requirements contained

in the ACC. There have been many changes to the public housing program since 1995, which require that PHAs be more familiar with specific regulatory requirements, and the 1969 or 1995 ACC versions may be inconsistent or misleading.

Comment: Commenters disagreed with HUD's ''redefining'' of the ACC as a grant agreement, and stated that the ACC is, and has always been, a contract, and should consistently refer to itself as such. A comment stated that Congress and HUD have consistently failed to view the existing public housing CACC as a contract and need to treat public housing contracts in the same way as the contracts for Project Based Section 8.

HUD Response: The Public Housing program, which was initially a loan program, was changed by Congress to a direct grant program in 1987, through which HUD awarded grants for the development and operation of public housing (see sections 112 and 119 of the Housing and Community Development Act of 1987, Public Law 100–242 (approved Feb. 5, 1988) (the HCD Act)). Consequently, in 1988, HUD implemented OMB Circular A–102, ''Grant Awards and Cooperative Agreements with State and Local Governments,'' by codifying its provisions in 24 CFR part 85 (March 11, 1988, 53 FR 8025, 8650). HUD made the public housing program subject to 24 CFR part 85. Below is the statement HUD made regarding Part 85 applicability to the public housing funding (53 FR 7875):

HUD previously took the position that annual contributions for public housing development and modernization were not subject to Circular A–102 requirements because the Federal assistance to public housing agencies (PHAs) was in the form of loans and loan guarantee commitments made by HUD. The Department's *current method of funding public housing development and modernization by means of capital grants* (as opposed to loans, as in the past) has the effect of subjecting public housing development and modernization funding to A–102 requirements. Public housing *operating subsidies are administered as grants* and therefore are also appropriate for A–102 grant management treatment [emphasis added].

Accordingly, as a result of the changes to the program made by the HCD Act, since 1988, HUD consistently administered the public housing program subject to the requirements of 24 CFR part 85 (until such requirements were superseded by the Uniform Guidance). In addition to codifying A–102 at 24 CFR part 85, HUD codified the provisions of OMB Circular A–133, ''Audits of States, Local Governments and Non-Profit Organizations,'' in 24 CFR parts 84 and 85 in 1997 (November 18, 1997, 62 FR 61617), and such other circulars related to grants management. In the intervening years since codifying the guidance in these circulars, HUD has cross-referenced applicable provisions of 24 CFR part 85 throughout program regulations, including applicable regulations for public housing development, modernization and operating funding.

The 1995 version of the ACC was revised against the backdrop of these above-mentioned statutory and regulatory requirements (*e.g.,* 24 CFR 941.103 (ACC definition), §§ 941.612, and 968.103). Consequently, the ACC, when it was revised in 1995 was an agreement related to the receipt of public housing grant funding. In 1998, when the public housing funding was fully converted to formula funding, HUD continued to use the same version of the ACC and continued to subject the formula funding and public housing program to the requirements of 24 CFR part 85. Nothing in the rulemaking processes for the Operating Fund regulation or the Capital Fund regulation changed the form of the funding that was being provided by HUD, and the Operating Fund and Capital Fund Rules specifically included and made applicable the requirements of Part 85. HUD's proposed changes to the ACC were consistent with Congressional intent first expressed 1987.

Comment: HUD is seeking to ''redefine'' terms to position themselves more favorably and insulate themselves from future challenges/litigation.

HUD Response: HUD notes the consistency of its position in litigation regarding the characterization of the federal financial assistance provided for the public housing. Furthermore, such funding is provided subject to a broad array of statutory and administrative requirements, including appropriations acts. HUD's changes to the ACC were not proposed in response to litigation, but HUD is aware of litigation surrounding the ACC. HUD makes clear in the current version that HUD has never contemplated money damages for action or inaction by HUD with respect to the ACC. Nothing in the revised ACC forecloses avenues for judicial relief from any HUD action that is arbitrary, capricious or contrary to law.

While the United States Court of Appeals for the Federal Circuit determined the Performance-Based Annual Contributions Contract (PBACC) to be a procurement contract, no such court has made such a determination with respect to the public housing ACC. In the absence of legislation to the contrary, HUD is required to continue to administer the public housing program consistent with the HCD Act of 1987, and other applicable requirements.

Comment: ''Operating Receipts'' and ''Program Receipts'' are interrelated terms, and changes to one affect the others. Commenters said that ''program receipts,'' previously called ''operating receipts,'' had been broadened. One commenter said ''this could potentially recapture de-federalized funds and require HUD approval for uses of all forms of income and proceeds produced by projects. The new definition restricts the use of all program and operation funds to public housing expenditures, which potentially captures de-federalized funds.'' Similarly, other commenters expressed concerns that ''the categories covered by 'program receipts' has been broadened and could potentially allow HUD to ''recapture de-federalized funds and require HUD approval for uses of all forms of income and proceeds produced by projects.'' Another commenter said ''[t]he definitions of Operating Reserves, Operating Costs, Operating Receipts, and Program Receipts are interrelated. HUD should explain and justify these definitions within the framework of the APA.'' More specific concerns related to the definition of Operating Receipts was that ''broadening this definition to include 'Program Receipts' results in controlling non-federal resources earned by PHAs and the refederalization of fees paid into a PHA's Central Office Cost Center.''

Finally, a number of comments expressed concerns about HUD's having ''restricted the definition of the term 'operating expenses' or 'operating expenditures' to those costs which may be charged against Operating Receipts in accordance with the CACC and HUD requirements.'' A commenter noted that ''[i]t is unclear what impacts these definition changes will have on reserves and offsets of reserve balances for operation expenses and . . . requests further clarity on these proposed changes as they appear to be an attempt to change statutory funding obligations.''

HUD Response: Operating Receipts is a term that was already defined in the 1995 version of the ACC. The changes between the 1995 ACC and the proposed ACC published in the 60-Day Notice were slight, and were made primarily to align the term with the Uniform Guidance, and to make the definition more consistent with 24 CFR

part 905, subpart F. Because PHAs are already bound by HUD regulations, including the requirements of the Uniform Guidance, HUD has deleted this definition from the ACC since it is adequately covered by regulations.

Additionally, HUD considers the following definitions: Operating Costs (Operating Expenditures or Operating Expenses), Operating Reserve, Program, Program Receipts, and Replacement Reserve Account, to be unnecessary due to regulatory coverage; and they have also been deleted. The determination of eligible costs and the use of program funds are covered by the Uniform Guidance and HUD regulations at Title 24 CFR, specifically those regulations at Parts 905 and 990.

As to concerns regarding the broadening of the term ''program receipts,'' HUD agrees that HUD cannot regulate PHA activity outside of the public housing program. However, program income (as that term is defined at 2 CFR 200.80), non-rental income (as covered by statute and by regulations determined by HUD), and proceeds from the sale of public housing real property are already subject to federal statutes and regulations. HUD has deleted the term ''program receipts'' as it is redundant of regulatory and statutory requirements. HUD has no intention of changing statutory funding obligations, and notes that public housing funding is subject to various statutory requirements, including funding requirements in the appropriations acts, HUD regulations, and the Uniform Guidance.

PHA Mission

Comment: Many commenters indicated that the PHA mission needs to be developed locally with public input and approval of its Board of Commissioners rather than by contract with HUD. Commenters noted that the addition of a requirement to comply with all applicable HUD requirements, coupled with changes in the proposed Section 3 of the ACC, unfairly imposes any HUD non-regulatory provisions, and the Mission statement should be removed.

HUD Response: The ACC mission statement incorporated the essential PHA requirements under Sections 2(a) and 3(a) of the 1937 Act, (42 U.S.C. 1437 note, and 1437a respectively), and has been part of the 1969 and 1995 ACC versions. By accepting public housing funds, the PHA makes itself subject to the statutory requirement that property funded with public housing assistance including dwelling units assisted with public housing funds be rented only to low income families. Because the mission statement is unnecessary and redundant of statutory and regulatory requirements, this section has been deleted from the ACC. PHAs are required to administer their Public Housing Funds in compliance with all ''Public Housing Requirements'' which include the 1937 Act, HUD regulations at Title 24 CFR, the Uniform Guidance, appropriations acts, and ''other federal statutes, regulations executive orders applicable to Public Housing Funds and Public Housing Projects,'' as they exist now and are amended in the future, whether or not those requirements are incorporated by reference in the ACC.

HUD Requirements

Comment: Most commenters objected to including HUD-issued notices, forms, and agreements as HUD requirements because, the commenters state, these requirements do not have a regulatory or statutory basis.

HUD Response: The HUD Requirements section was added to the ACC as a reminder. PHAs are already required in the 1995 version of the ACC to comply with ''all applicable laws, executive orders, and regulations that are not specifically incorporated [in the ACC] by reference''; and under 24 CFR 905.108, to comply with HUD-issued ACC and amendments, HUD notices, all applicable federal statutes, executive orders and regulatory requirements, as amended. All required forms are issued through the Paperwork Reduction Act process with public opportunity to comment or are required by the regulations, which were properly promulgated under the APA. However, to lessen confusion, the HUD Requirements section has been deleted from the ACC, and the term ''HUD Requirements'' has been replaced with the term used in existing regulations at 24 CFR 905.108, ''Public Housing Requirements.''

Comment: MTW PHAs stated that requiring compliance with HUD's notices, forms, and agreements would reduce MTW flexibilities.

HUD Response: The MTW Standard Agreement contains a provision that it ''supersedes the terms and conditions of one or more ACCs between the Agency and HUD, to the extent necessary for the Agency to implement its MTW demonstration initiatives as laid out in the Agency's Annual MTW Plan, as approved by HUD.'' This provision covers regulatory or statutory waivers granted under the MTW Agreement and provisions in PIH notices implementing provisions thereof to the extent of a conflict between the authorized MTW activity and the Public Housing Requirement. The MTW ACC amendment for the MTW expansion, similarly, amends the ACC to the extent necessary to allow the agency to participate in the MTW demonstration in accordance with the MTW Operations Notice. Because the MTW ACC Amendment requires compliance with all HUD requirements not exempted by the MTW Operations Notice, language has been added to that document to clarify the applicability of subregulatory guidance impacting MTW authorizations.

Cooperation Agreement

Comment: ''HUD should not have prior approval of Cooperation Agreements entered into with local governments to address local needs. Ratification or review to protect federal interest should be sufficient. HUD has no right to inject itself into local negotiations over changes to Cooperation Agreements.'' One commenter also noted that ''HUD's proposed involvement in local cooperation agreements will potentially upend 'win-win' arrangements between PHAs and local governments that have ultimately benefited its tenants and communities for years.'' Additionally, one commenter noted that ''[w]hile Section 4 of the proposed ACC requires a Cooperating [sic] Agreement to be in effect, Cooperation Agreements do not apply to mixed finance projects that have made an election pursuant to Section 35(f) of the United States Housing Act of 1937, as amended.''

HUD Response: HUD's requirement concerning a local cooperation agreement is authorized by statute and regulations. Specifically, Section 5(e)(2) of the of the 1937 Act provides that Federal financial assistance to PHAs shall not be made unless the governing body of the locality involved enters into an agreement with the PHA providing for the local cooperation required by the 1937 Act. In order to implement this requirement, HUD requires PHAs to comply with the provisions of a Cooperation Agreement in the form prescribed by HUD, which form has not changed since 1968; and not terminate or amend the Cooperation Agreement without prior written approval of HUD. HUD has a statutory obligation to monitor and ensure the proper use of public housing funds. However, in light of HUD's determination that this agreement should not unnecessarily repeat statutory or regulatory requirements, the proposed Section 4 has been deleted as the requirement for the HUD-prescribed Cooperation Agreement is in the 1937 Act, and HUD implementing regulations at 24 CFR part 905.

The ACC provides general terms that apply to all housing authorities. As noted by the commenter, Section 35(f) of the 1937 Act allows for a PHA to choose to exclude mixed finance projects from the Section 6(d) tax exemption and the Cooperation Agreement. If a PHA does not make that election, a Cooperation Agreement is required. If a PHA makes that election, HUD regulations implement this requirement at 24 CFR 905.606(a)(8), and an express statement is not needed.

Declaration of Restrictive Covenants

Comment: One commenter stated that the ''DOT [Declaration of Trust] signed by the PHA restricts the use of the units deeded to the PHA. Units are to be used by low-income families.'' Another comment noted that the use of ''shall'' in the proposed Section 5.a means this is a requirement (vs. prior 1995 version that said ''may''), and that ''HUD ought to clarify its reasoning behind this modification as it removes PHA discretion and as such may negatively impact current project implementation.''

HUD Response: The proposed Section 5 was updated to reflect statutory and regulatory requirements that have been in effect since the public housing program was a loan program—namely the use of restrictive covenants to ensure the long-term use restrictions mandated by the 1937 Act. For more than 30 years the form instrument prescribed by HUD was a ''Declaration of Trust.'' See Form HUD–52190 (current DOT form available at *https://www.hud.gov/hudclips*). The requirement that the Declaration of Trust be the first recorded document against public housing property is longstanding and ensures the long-term use of public housing projects by low-income families. See 24 CFR 905.108 (definition of Declaration of Trust), 905.304, and 905.505(c)(4). The use of ''may'' in Section 5.a of the 1995 version of the ACC applies to the form of the instrument but not to the requirement for order of recordation. Because of the mixed-finance program, HUD began to allow the use of other HUD-approved instruments otherwise known as declarations of restrictive covenants, and the change in language is not intended to change this practice; however, the recordation requirement is long-standing, and any exceptions have always required HUD approval.

Comment: One commenter said ''[t]hough Section 5.b of the proposed ACC requires a declaration be recorded against the Project 'prior to the recordation of any other encumbrance,' such requirement is inconsistent with HUD's practice, and we advise HUD to instead require such only 'unless otherwise approved by HUD.' ''

HUD Response: The general requirement for any form of restrictive covenant is that it be the first recorded document. See 24 CFR 905.505(c)(4). We believe waiver of the ACC provision (now located at Section 4—Restrictive Covenants) is sufficient to allow HUD to approve, after a finding of good cause, those circumstances when a restrictive covenant is not recorded prior to the recordation of other encumbrances.

Disposition and Encumbrances

Comment: A commenter stated as to proposed Section 6:

- *6.a:* The general covenant against disposition and encumbrances does not acknowledge that mixed finance projects will need to enter into mortgages, use restrictions, and other encumbrances to finance the projects. Accordingly, we would recommend HUD clearly state that mixed finance projects will instead only be subject to the provisions contained in the proposed Section 6.b.
- *6.b:* Modifications are required in order to be consistent with the standard language in prior HUD mixed finance deals that has been vetted extensively with lenders and investors.

HUD Response: The HUD regulations at Title 24 CFR (in particular those provisions at 24 CFR part 905, subpart F) address the concerns raised by the commenter. HUD has not incorporated any mixed-finance specific language in the revised ACC. However, in response to comments HUD has revised the model Mixed-Finance Amendment. To the extent PHAs need commitments for mixed finance approvals beyond what is stated in the ACC, HUD will continue to work with PHAs on project-specific solutions, including the use of a mixed-finance amendment, adding language to the Regulatory and Operating Agreements that are required for a mixed-finance development, or adding language to the restrictive covenant.

HUD notes that it has revised the proposed published version of Section 6. Additionally, Section 3 of the revised ACC published herein makes specific reference to the Public Housing Requirements, which include 42 U.S.C. 1437p and HUD regulations at 24 CFR part 970.

Comment: One commenter included a markup of proposed Section 6:

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6. Disposition and Encumbrances.

a. *Covenant Against Disposition and Encumbrances.* The HA shall not demolish or dispose of any project, or portion thereof, other than in accordance with the terms of the CACC and applicable HUD Requirements. With the exception of entering into dwelling leases with eligible families for dwelling units in the Projects covered by the CACC, except as set forth in a Mixed-Finance declaration, mortgages identified in a Mixed-Finance amendment, and normal uses associated with the operation of the Project(s), the HA shall not in any way encumber any project, or portion thereof, without the prior written approval of HUD. In addition, unless approved in advance and in writing by HUD, the HA shall not pledge as collateral for a loan the assets of any Project covered under the CACC.

b. *Mixed-Finance Projects.* No transfer, conveyance, or assignment shall be made without the prior written approval of HUD of: (i) any interest of a managing member, general partner, or controlling stockholder (any such interest being referred to as a "Controlling Interest") of the Owner Entity; or (ii) a Controlling Interest in any entity which has a Controlling Interest in the Owner Entity; or (iii) prior to the payment in full of all equity contributions described in the approved evidentiary documents, other than equity contributions made solely for the purpose of paying developer fees, any other interest in the Owner Entity, or in any partner or member thereof. The term "Controlling

1. Notwithstanding the foregoing, HUD consent is not required ~~where a business organization that has~~ for the transfer of a limited interest (non-controlling and non-managing) in the Owner Entity ~~transfers a non-controlling and non-managing interest in~~ or in any partner, member or stockholder of the business organization holding such limited interest, provided that the Owner Entity: (i) provides HUD with written notice of such transfer; and (ii) certifies to HUD that the new owner of the limited interest remains obligated to fund its equity contribution in accordance with the terms of the HUD-approved organizational documents of the Owner Entity.

2. HUD will not unreasonably withhold, delay, or condition a request by the Owner Entity for HUD's consent to an internal reorganization of the corporate, company or partnership structure of the Owner Entity or any of the partners, members or stockholders of the Owner Entity.

3. Notwithstanding the foregoing, the prior approval of HUD and the HA will not be required for the exercise by any investor member or partner of the Owner Entity ("Investor") of its right pursuant to the ~~Amended and Restated Limited~~ Operating Agreement or Partnership Agreement of the Owner Entity (an Operating Agreement or Limited Partnership Agreement referred to herein as a "Partnership Agreement") to remove the managing member or general partner (a managing member of a limited liability company or the general partner of a limited partnership referred to herein as a "General Partner") of the Owner Entity and appoint the Investor or its Affiliate (i.e., any entity which directly or indirectly controls, or is controlled by, or is under common

control with, the specified entity) as an interim ~~general partner~~ General Partner of the Owner Entity so long as the Investor gives prompt written notice to HUD of such removal and appointment ("Removal Notice"); provided that HUD and the HA consent will be required for the appointment of such interim ~~general partner~~ General Partner to extend beyond a ninety (90) day period and for the appointment of any entity (including the Investor of an ~~affiliate~~ Affiliate thereof) as the permanent replacement ~~general partner~~ General Partner. Such 90-day period will commence on the date of the Removal Notice ("Interim Replacement Period"). With the prior written approval of HUD and the HA, the Interim Replacement Period may be extended for an additional 90 days to allow the substitute ~~general partner~~ General Partner of the Owner Entity to find a replacement ~~general partner~~ General Partner acceptable to HUD and all other parties, provided that prior to the expiration of such additional 90-day period, the substitute ~~general partner~~ General Partner demonstrates that the Investor is continuing to fund (or has already funded) capital as required under the Partnership Agreement and that the Project continues to be operated in a manner consistent with HUD Requirements.

4. The consent of HUD and the HA will not be required for (i) any exercise by the Investor of its right to require the repurchase of its investor member or limited partnership interests as against the General Partner, any guarantor, and/or any affiliate thereof ("Repurchaser") pursuant to the Partnership Agreement, provided that the Investor provides prompt written notice to HUD and the HA at the time of its exercise of such right, and further provided that any resale of the investor member or limited partnership interests by the Repurchaser will be subject to the approval of HUD and the HA, such approval not to be unreasonably withheld, delayed or conditioned, or (ii) the

exercise by the HA (or any approved Affiliate thereof) of its rights to acquire interests or the Property pursuant to the Right of First Refusal and Purchase Option Agreement of approximately even date herewith.

5. HUD and the HA authorize the Controlling Interest to collaterally assign and pledge its interest in the Owner Entity to a construction and/or permanent lender, and to allow a construction and/or permanent lender to exercise any of its rights pursuant thereto, so long as the construction and/or permanent lender gives prompt written notice to HUD of the exercise of such rights at the time of such exercise (the "Pledge Notice"). However, the consent of HUD and the HA shall be required for the appointment of any substitute Controlling Interest (including construction and/or permanent lender or its Affiliates) extending beyond a 90-day period. Such 90-day period will commence on the date of the Pledge Notice (the "Pledge Replacement Period"). With notice to the HA and notice and prior written approval of HUD, the Pledge Replacement Period may be extended for an additional 90 days to allow the substitute Controlling Interest of the Owner Entity to find a replacement Controlling Interest acceptable to HUD and the HA provided that prior to the expiration of such additional 90-day period, the substitute Controlling Interest demonstrates that the Investor is continuing to fund (or has already funded) its equity contribution as required by the Partnership Agreement and that Project continues to be operated in accordance with the Applicable Public Housing Requirements.

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HUD Response: As previously stated, HUD has decided not to incorporate any mixed-finance specific language in the revised ACC but has revised the model Mixed-Finance Amendment. To the extent PHAs need commitments for mixed finance approvals beyond what is stated in the ACC, HUD will continue to work with PHAs on project-specific solutions, including the use of a mixed-finance amendment, adding language to the Regulatory and Operating Agreements that are required for a mixed-finance development, or adding language to the restrictive covenant.

Insurance

Comment: HUD failed to allow for PHA's professional judgment on risk and cost benefit of various types of insurance as well as ignoring state law on tort immunity. Commenters requested that HUD indicate what is adequate coverage. Commenters stated it is unnecessary for HUD to collect and monitor Certifications of Insurance.

HUD Response: HUD's primary concern is making sure that public housing projects acquired, developed and assisted with federal assistance, and public housing assets are covered from losses. This provision has been in place since the 1969 ACC. The list of mandatory and recommended, but optional insurance is consistent with, or required by, 2 CFR 200.447 and 24 CFR

965 subpart B, and identifies those ''costs of insurance required or approved and maintained, pursuant to the Federal award'' that are allowable (2 CFR 200.447(a)). To further assist PHAs in understanding HUD's intentions, HUD refers PHAs to its explanatory guidance on insurance in PIH Notice 2016–13.

HUD will continue to require Certifications of Insurance and require that PHAs keep copies of it in their records, and make them available for inspection, subject to Public Housing Requirements. The revised ACC removes the process of establishing a PHA self-insurance fund, because 24 CFR 965.205(c) details this process.

Employer Requirements

Comment: Various commenters noted that a provision appearing in a previously proposed ACC limiting the use of funds made available under the 1937 Act for the salary, including bonuses, for PHA employees (30-day notice published on September 6, 2017 at 82 FR 42106) is not included in the proposed ACC. These commenters assert that the elimination of this provision reflects HUD's understanding that it lacks Congressional authorization to limit the use of funds made available under the 1937 Act for PHA employee salaries.

HUD Response: HUD disagrees with commenters asserting that HUD lacks Congressional authorization to limit the use of funds made available under the 1937 Act for PHA salaries; since Federal Fiscal Year (FFY) 2012, through HUD appropriations, Congress has imposed limits on the amount of Section 8 HCV and Section 9 funds PHAs may use for employee salaries. PIH Notice 2016–14 and PIH Notice 2018–13 detail PHA salary limitations and PHA reporting responsibilities. Additionally, for FY 2019, division G, title II, section 222 of the Consolidated Appropriations Act, 2019 (under the heading ''General Provisions—Department of Housing and Urban Development'') states: ''None of the funds made available by this Act, or any other Act, for purposes authorized under section 8 (only with respect to the tenant-based rental assistance program) and section 9 of the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*), may be used by any public housing agency for any amount of salary, including bonuses, for the chief executive officer of which, or any other official or employee of which, that exceeds the annual rate of basic pay payable for a position at level IV of the Executive Schedule at any time during any public housing agency fiscal year 2019.'' PHAs remain subject to the provisions contained in HUD appropriations, regardless of incorporation into the Terms and Conditions agreement pursuant to Section 2 of the revised ACC.

Accounts, Records, and Government Access

Comment: Section 9.b: Commenters state that the proposed Section 9.b would interfere with PHA compliance with information requests pursuant to FOIA or local open records laws by requiring prior HUD approval before releasing information contained in HUD's systems of records. A few commenters express doubt that HUD would have the capacity to track and approve PHA submissions and requests in a timely fashion. A few commenters state that requiring HUD approval prior to a release of records, especially in response to a valid information request, could subject a PHA to liability for denying a request. Additionally, the proposed provision could make it more difficult for law enforcement entities to conduct investigations of issues such as public benefit fraud.

One commenter stated that the proposed Section 9 does not make it clear that Section 9.b refers only to data held within HUD's systems of records. Another commenter states that section 9 would inhibit a PHA from operating in a transparent manner by limiting the release of information to stakeholders. A number of commenters assert that, as independent entities and political subdivisions of States, PHAs are not subject to HUD's control relating to transparency to the public.

Comment: Section 9.c: Numerous commenters assert that the proposed Section 9.c of the proposed ACC would expose privileged communications, records, and information, including records protected by attorney-client privilege, to HUD examination.

Comment: Section 9.e: Several commenters state that the proposed Section 9.e of the ACC could impact the ability of PHAs to engage in data-sharing agreements and other arrangements with third-party services providers. One MTW PHA expresses concern that the proposed provision would hinder its ability to monitor, evaluate, and understand policy questions that guide its MTW activities. Numerous commenters stated that the proposed Section 9.e of the proposed ACC is overly broad and would open all records of a PHA agent or contractor, not just those records of work supporting the operation of public housing, to HUD inspection. These commenters assert that PHA contractors and partners will terminate their relationships with PHAs to protect their confidential records. Alternatively, a couple of commenters state that PHAs might have to pay higher costs to contractors or use substandard contractors because of the HUD record inspection requirements contained in the proposed Section 9.e. Several commenters express concern that HUD might misuse its access to contractor records to obtain records outside of HUD's authority. A few commenters suggest that the phrase ''assists in fulfilling any obligation under this CACC'' is too broad and would capture too many activities. A couple of commenters assert that HUD would make PHAs liable for the actions of independent contractors and that it is unreasonable to impute contractor actions to a PHA that could be deemed a PHA violation of the ACC.

HUD Response: HUD notes that the proposed Section 9 (or a similar provision) has been included in the 1969 and 1995 versions of the ACC. The change in language in the proposed 2018 version was to remind PHAs of their responsibility to make information available consistent with applicable statutory and administrative requirements, and that the maintenance of information and the prohibition on sharing particular information, such as tenant data, is prohibited by the same or similar statutory and administrative requirements, including regulations issued by HUD at title 24 CFR. HUD has removed the proposed Section 9 from the ACC because PHAs remain subject to statutory and regulatory recordkeeping and monitoring requirements (including HUD notices on HUD's system of records (SORN) (*e.g., https://www.hud.gov/sites/documents/DOC_15179.PDF,* and *https://www.hud.gov/program_offices/officeofadministration/privacy_act/pia/fednotice/SORNs_LoB#pih)* in connection with the use of financial assistance provided pursuant to the 1937 Act. HUD recognizes attorney-client privilege as a longstanding common law protection, and HUD does not unduly compel PHAs to disclose privileged or work product protected information. However, HUD reminds PHAs that the disclosure of information related to the public housing program is required to be shared for various reasons.

Section 5(h)(1) of the 1937 Act (42 U.S.C. 1437c(h)(1)) provides that when a PHA carries out activities using financial assistance provided pursuant to the 1937 Act for the operation, modernization, and development of public housing, the PHA must allow HUD access to books, documents, and

records related to the activities. Section 5(h)(1) of the 1937 Act and 2 CFR 200.336 also require that the HUD Inspector General, Comptroller General of the United States, and all of their authorized representatives, have the right to inspect a PHA's records that pertain to a public housing award. In the context of audits, pursuant to 2 CFR 200.501(g), PHAs are ''responsible for ensuring compliance for procurement transactions which are structured such that the contractor is responsible for program compliance or the contractor's records must be reviewed to determine program compliance.'' To the extent that a PHA contractor is responsible for public housing program compliance (*e.g.,* under a management contract), PHAs are responsible for ensuring that the contractor has adequate records. More specific recordkeeping requirements include, but are not limited to, the requirements at 24 CFR 905.326 and 990.325.

Other 1937 Act statutory requirements that concern recordkeeping or information sharing include section 42 U.S.C. 1437y (Provision of information to law enforcement and other agencies) and 42 U.S.C. 1437n(e)(C)(4). Additionally, pursuant to Section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988 (''McKinney Homeless Amendments''), tenant and participant income information required or necessary to be collected by a PHA, for the purpose of verifying income information pertinent to the applicant's or participant's eligibility or level of benefits, must be kept under the terms of the Privacy Act, as such terms are made applicable by HUD. The McKinney Homeless Amendments are implemented at 24 CFR part 5. Pursuant to 5 CFR 5.212(a), ''[t]he collection, maintenance, use, and dissemination of [social security numbers] SSNs, [Employer Identification Numbers] EINs, any information derived from SSNs and . . . EINs and income information under this subpart shall be conducted, to the extent applicable, in compliance with the Privacy Act (5 U.S.C. 552a) and all other provisions of Federal, State, and local law. Thus, regardless of local open records laws, PHAs must retain records in compliance with the McKinney Homeless Amendments the Privacy Act as provided at 24 CFR part 5; other Public Housing requirements, including HUD SORNs; and are required to get HUD approval to release information maintained in HUD databases such as PIC.

Depository

Comment: Commenters stated that this section imposes federal deposit and investment requirements on defederalized and non-federal fees paid to PHAs' COCC, as well as contributions from affiliates and subsidiaries. These commenters stated that HUD does not have the authority to so impose such requirements.

HUD Response: Commenters misread the coverage of this requirement and HUD's changes. The General Depository Agreement (GDA) (HUD–51999) has been a requirement in the 1969 and 1995 ACC versions. The GDA is just one part of HUD's implementation requirements imposed on HUD with regard to the disbursement of federal funds before such funds have been expended. Additionally, the GDA requirement applies to Public Housing Funds, disposition proceeds and program income, and other funds that are restricted, by statute or regulations, in their use, and/or are received by or held for the account of the PHA in connection with the development, operation, improvement and disposition of its public housing property. These funds are to be insured or fully and continuously collateralized above the federal insurance limits per the General Depository Agreement and Department of the Treasury statutes and regulations, including but not limited to 31 CFR part 202. HUD has slightly revised this section in the ACC.

The changes to the ACC are not intended to address any future changes to the Public Housing requirements regarding COCC.

HUD in Possession of Project(s)

Comment: Commenters stated that the proposed ACC must clarify that a PHA's decision to subject its mixed-finance public housing units to real estate taxes should not result in a violation of section 14.b(6) of the ACC published in the 60-Day Notice, which states that ''termination of tax exemption (either real or personal property) on behalf of a Project covered under the CACC'' constitutes a substantial default. Commenters also recommend HUD insert the following sentence to the proposed section 14.e to ensure HUD will not disturb a compliant mixed finance Owner Entity's rights: ''Notwithstanding the forgoing, for Mixed Finance projects, so long as the Owner Entity shall not be in default of its obligations related to such a project, HUD shall not exercise any rights under this sub-section 13.e. in such a manner as to disturb the Owner Entity's and other participating parties' rights under any Project agreements.''

HUD Response: The proposed Section 14 has been removed from the ACC. HUD believes the provision is essentially redundant of requirements at title 24 of the CFR, specifically 24 CFR part 907. However, HUD has retained in the new section 9 (Substantial Default) the standard for default under such ACC. Section 9 does not retain the specific requirements for mixed finance public housing projects, which are included in the model Mixed-Finance Amendment. The ACC provides general terms that apply to all housing authorities. To the extent PHAs need commitments for mixed finance approvals beyond what is stated in the ACC, HUD will continue to work with PHAs on project-specific solutions, including the use of a mixed-finance amendment, adding language to the Regulatory and Operating Agreements that are required for a mixed-finance development, or adding language to the restrictive covenant. Whatever the project-specific solution, HUD would continue to make clear that a PHA that subjects its mixed-finance public housing units to real estate taxes is not in a violation of Public Housing requirements.

Conflict of Interest

Comment: Many commenters objected to what was mistakenly understood to be a ''new written conflict of interest'' standard for board members. Commenters also stated that HUD lacks the authority to impose such a requirement and the requirement may conflict with existing state and local conflict of interest requirements involving public officials.

HUD Response: This is not a new conflict of interest standard for board members. Sections 19 and 515 respectively, of the 1995 and 1969 versions of the ACC had conflict of interest provisions that covered board members. Section 15.a. of the proposed ACC provides that PHAs must maintain written standards of conduct covering conflicts of interest and governing the performance of its board members, executives, and employees engaged in the administration and operation of Projects covered by the ACC. This requirement is consistent with the Uniform Guidance at 2 CFR 200.112 and 200.318, which requires that PHAs maintain written standards of conduct covering conflicts of interest. For clarity HUD has revised the provision at Section 8 of the ACC. Because PHAs are already bound by the Uniform Guidance, HUD revised the section to reflect coverage when PHAs are using

public housing funds for its procurements (as required by the Uniform Guidance); HUD includes members and delegates to Congress in the covered classes for purposes of evaluating conflicts in PHA hiring and procurement. Additionally, Section 8.e of the revised ACC repeats the language in Section 14 of the 1995 version that public housing funds cannot be used ''to pay any compensation for the services of members of the PHA's Board of Commissioners.''

Civil Rights and Employment Requirements

Comment: A number of commenters stated that a sentence in the Section 16.d of the proposed ACC, ''Civil Rights and Employment Requirements,'' should be removed as irrelevant: ''The HA may, consistent with applicable law and regulation, utilize work requirements when and where appropriate.'' One commenter added that the inclusion of this sentence could confuse PHAs and result in the implementation of polices that harm vulnerable families.

HUD Response: HUD agrees with commenters that the inclusion of the sentence would have been confusing; additionally, consistent with HUD's removal of provisions that repeat existing statutory and regulatory requirements, the proposed Section 16 has been removed from the final ACC, but it has been retained in part and moved to Section 6 of the ACC. Additionally, HUD includes by reference under Section 2 (Public Housing Administration) PHA obligations to comply with statutory and regulatory civil rights requirements. PHAs are also reminded that section 5A of the 1937 Act states that PHAs ''will carry out the public housing agency plan in conformity with title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d *et seq.*], the Fair Housing Act [42 U.S.C. 3601 *et seq.*], section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], and title II of the Americans with Disabilities Act of 1990 [42 U.S.C. 12131 *et seq.*], and will affirmatively further fair housing.''

Waiver or Amendment

Comment: A commenter suggested a need for an expiration date for waivers and amendments to be agreed to in writing by HUD and the PHA. Another commenter suggested that HUD must seek written agreement from HAs to any proposed changes. Other comments noted that the ''most responsible approach for HUD to take is for it to negotiate the revision of the ACC with industry groups who then, if the negotiations are fruitful, encourage their members to agree to the amendments.'' Commenters stated that ''the revised ACC provides that the contract can be amended in writing, presumably only by HUD. Such a contract is an illusory contract.'' Commenters stated that [t]he appropriate method to implement a new CACC would be to work with representatives of local housing authorities to arrive at a mutually agreeable product that could be adopted by PHAs without controversy.''

HUD Response: Section 19 of the proposed ACC published in the 60-Day Notice stated that ''[t]his agreement may be amended in writing.'' This provision was not intended to provide HUD with the ability to unilaterally revise the ACC during its term. Pursuant to section 6(a) of the 1937 Act, HUD is authorized to change the ACC terms and conditions as the Secretary deems necessary, but these changes will not alter the ACC terms and conditions applicable to prior year public housing funds. In response to the comments, HUD has revised the ACC to make clear that a PHA may request an amendment to the ACC. Additionally, upon a request of a PHA, HUD may waive administrative provisions in the ACC, based on a finding of good cause. HUD cannot waive statutory prohibitions.

Paperwork Reduction Act (PRA), Administrative Procedures Act (APA), and Negotiation

Comment: A few commenters state that use of the Paperwork Reduction Act (''PRA'') is not a legitimate means with which to promulgate public comment on the proposed ACC. A number of commenters assert that the proposed ACC does not collect information, so the PRA does not apply. Many commenters add that PRA standards for public comments do not satisfy Administrative Procedures Act requirements. As noted by a few commenters, while the **Federal Register** PRA notice provides a description of proposed ACC revisions, it does not provide an explanation of the underlying rationale, public policy purpose or benefits, or statutory or regulatory basis of the proposed ACC revisions. Additionally, these commenters assert that PRA does not require HUD to formally respond to comments received. A few commenters state that HUD's actions in revising the ACC are ''arbitrary and capricious,'' and they assert that the proposed ACC **Federal Register** notices have been deceptive. Finally, several commenters criticize HUD's burden hour chart and cost estimate as being unrealistic.

A number of commenters state that HUD must promulgate changes to the public housing ACC pursuant to Administrative Procedures Act (APA) rulemaking rather than pursuant to PRA. Several commenters added that statutory changes may also be required because the proposed ACC includes significant substantive changes from the prior ACC.

HUD response: Information collection can occur by a number of vehicles in addition to standard government forms. As discussed above, the Public Housing program has been a grant program since 1987. The ACC is an information collection under the definitions in 5 CFR 1320.3(c)(1), which states that a collection of information may be in any form or format, including an agreement. The ACC is a form with an OMB form number; therefore, review and public comment under the PRA are appropriate.

Contrary to statements in the comments, the PRA process does require solicitation of and response to public comments (see 5 CFR 1320.5(a)(1)(F) (requiring ''A summary of the public comments received under § 1320.8(d), including actions taken by the agency in response to the comments''). In fact, HUD received 79 comments and is here responding to the issues raised as well as providing its rationale for proposed ACC revisions. HUD revises the ACC pursuant to its inherent authority under the Department of Housing and Urban Development Act (42 U.S.C. 3531 *et seq.*), and section 6 of the 1937 Act. A primary purpose of this revision is to minimize the scope of the requirements contained in the ACC and to ensure that Public Housing requirements are uniformly applied. More than 400 PHAs continue to operate under the 1969 version of the ACC. The revised ACC ensures that the Uniform Guidance is applied consistently, and that all PHAs are subject to the same terms and conditions applicable to the receipt of public housing funds.

Regarding the assertion that the proposed ACC **Federal Register** notices have been deceptive, HUD has taken steps to clearly identify the provisions that have been deleted, revised or retained. However, the ACC should be reviewed in its entirety to determine the exact nature and scope of any revisions.

As to the comment on the burden hour statement, HUD's prior experience indicates that it is reasonable.

Comment: Some commenters argue that even if HUD followed APA rulemaking requirements, APA rulemaking is not the appropriate method by which to amend the public housing ACC because a regulation cannot override or amend contract terms. A couple of commenters assert that HUD must withdraw the proposed ACC and negotiate revisions to the 1995 ACC with PHAs. One commenter asserts that the proposed ACC needs to be reviewed by ''an independent legal authority'' to determine its fairness and compliance with statutes.

HUD response: Pursuant to section 6(a) of the 1937 Act, and section 200.38(b) of the Uniform Guidance, the Secretary has the authority to include in the ACC such covenants, conditions, or provisions as he may deem necessary in order to insure the low-income character of public housing projects and that PHAs act in accordance with Public Housing requirements; the Secretary is not obligated to negotiate with PHAs as it is within his discretion what terms and conditions related to the federal award are ''necessary.'' Accordingly, the Secretary, through the ACC, establishes the necessary terms and conditions related to the award of public housing funds. The terms and conditions of the ACC published in this notice do not override or amend prior versions of the ACC. The ACC terms and conditions apply to a PHA's public housing funding received after execution. Prior awards of public housing funding received by a PHA while subject to either the 1969 or 1995 ACC will continue to be governed by the terms of those ACCs. To the extent commenters were concerned that the ACC did not comply with relevant statutes, the revised ACC minimizes the scope of the ACC requirements, and eliminates the recitation of specific statutory and regulatory requirements. As noted earlier, the PRA process requires solicitation of and response to public comments.

Implementation of ACC

Comment: Several commenters stated that the new ACC must include Board and Executive review and approval and signature by both HUD and Housing Authorities.

HUD Response: The ACC serves as notice of the terms and conditions that attach to HUD's award and the PHA's request for, acceptance, and use of federal financial assistance. Execution of the ACC represents acceptance of those terms and conditions undergirding all instruments subsequently executed to provide public housing funding, including, but not limited to SF–424 forms, Operating Fund budget letters, competitive grant agreements, etc. Pursuant to Section 1.a of the ACC published in this notice, such funding instruments will be incorporated into the ACC as amendments or funding exhibits.

HUD agrees that entering into the ACC requires Board and Executive Review. HUD expects the Board and Executive Review approval would be conducted as part of same process engaged by PHAs before making submissions for financial assistance through the Operating Fund and Capital Fund formulas (*e.g.,* using an SF–424 form). Electronic signatures are permissible for HUD programs, and that option will be made available for the ACC; however, HUD has added a signature line for PHAs on the revised form for those PHAs that prefer or are required under State law to effectuate agreements by a wet signature.

Comment: Two commenters did not think that drawing down funds should result in an agreement between HUD and the PHA. One argued that PHA staff lack authority to bind the PHA, which could make the agreement unlawful or against the PHA's internal governing procedures.

HUD Response: A PHA's drawdown of funds is a certification by the PHA that the funds are being drawn for, or in connection with, an eligible activity under the public housing program. Federal financial management requirements are based on the presumption that the personnel in a PHA's organization who drawdown funds are authorized to do so. Consequently, PHA employees should not be drawing down funds or taking any other actions on behalf of the PHA without proper authority. Every draw down or use of funding must be in compliance with HUD statutes, regulations and other HUD requirements. It is incumbent on PHAs (not HUD) to ensure that PHA personnel are authorized to act on their behalf.

Moving to Work

Comment: MTW agencies commented that HUD was precluded from revising the ACC by the 2016 appropriations act language extending the current MTW agreements and by language regarding the ACC in the MTW Standard Agreement.

HUD Response: HUD disagrees. The new ACC does not amend the MTW Standard Agreement. The MTW Standard Agreement provision stating that the agreement supersedes the terms of the ACC to the extent of a conflict between the ACC and a HUD-approved MTW activity continues to apply to the new ACC.

Comment: MTW agencies raised concerns that the new ACC would change the funding formulas provided under those agreements and that it would allow HUD to circumvent statutory requirements regarding offsets of MTW PHA reserves.

HUD Response: The funding language in Attachment A of the MTW Standard Agreement varies among MTW agencies. The majority of MTW agencies do not have a unique funding formula for public housing funds in their MTW agreements and receive public housing funds in accordance with the same formulas and requirements as non-MTW PHAs. Agencies with specific alternative formulas for public housing funds in their MTW Agreements continue to have those same provisions in their MTW Agreements under the new ACC. Further, the MTW Agreements were amended in 2016 to incorporate the statutory provision prohibiting offset of reserves equal to four months of operating expenses.

G. Chart Summarizing Statutory or Regulatory Public Housing Requirements Deleted From the ACC Proposed in the 60-Day Notice

60-Day notice proposed ACC	30-Day notice proposed ACC	Existing public housing requirements that apply to *deleted* portions of the 60-Day notice proposed ACC
Sec. 1—Definitions	Deleted	''Cooperation Agreement'' (24 CFR 905.108); ''Operating Costs'' (24 CFR 990.115); ''Operating Receipts'' (2 CFR 200.80, Sec. 9(k) and Sec. 18(a)(5) of the 1937 Act); ''Program Receipts'' (2 CFR 200.80); ''Public Housing'' (24 CFR 905.108); ''Replacement Reserve Account'' (Sec. 109 of HOTMA, P.L. 114–201).
Sec. 2—Mission of HUD and HA	Deleted	Sec. 2(a), Sec. 3(b)(1) (''low-income housing'' and ''public housing'') and Sec. 3(b)(6) (''Public Housing Agency'') of the 1937 Act.

60-Day notice proposed ACC	30-Day notice proposed ACC	Existing public housing requirements that apply to *deleted* portions of the 60-Day notice proposed ACC
Sec. 3—HUD Requirements	Sec. 2—Public Housing Administration (deletes compliance with HUD notices).	''Public housing requirements,'' 24 CFR 905.108.
Sec. 4—Cooperation Agreement(s)	Deleted	Sec. 5(e)(2) of the 1937 Act and 24 CFR 905.108.
Sec. 5—Declaration of Restrictive Covenants	Sec. 4—Restrictive Covenants (deletes description of instrument terms and mixed-finance provisions).	Sec. 9(d)(3) and 9(e)(3) of the 1937 Act and 24 CFR 905.108 (''Declaration of Trust,'' ''Declaration of Restrictive Covenant''); 24 CFR 905.304(a); and 24 CFR 905.505(c); [Mixed-finance provisions will be included in a mixed-finance ACC amendment].
Sec. 6—Disposition and Encumbrances	Sec. 3—Encumbrances (deletes general disposition requirements and mixed-finance provisions).	Sec. 18 of 1937 Act and 24 CFR part 970 [Mixed-finance provisions will be included in a mixed-finance ACC amendment].
Sec. 7—Insurance Requirements	Sec. 5—Insurance Requirements (deletes self-insurance provision and mixed-finance provisions and optional insurance coverage).	24 CFR 965.205(c) [Mixed-finance provisions will be included in a mixed-finance ACC amendment].
Sec. 8—Employer Requirements Sec. 16—Civil Rights and Employment Requirements	Sec. 6—Civil Rights and Employer Requirements (deletes civil rights provisions summarizing civil rights requirements).	Civil rights laws, e.g., Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d; 24 CFR part 1); the Fair Housing Act (42 U.S.C. 3601–3619; 24 CFR part 100); section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794; 24 CFR part 8); (the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107; 24 CFR part 146); the Americans with Disabilities Act (Pub. L. 101–336, approved July 26, 1990; 28 CFR part 35); Executive Order 11063 on Equal Opportunity in Housing (24 CFR part 107); Executive Order 11246 on Equal Employment Opportunity, as amended by Executive Order 11375 (41 CFR part 60); and Executive Order 12892 on Affirmatively Furthering Fair Housing.
Sec. 9—Accounts, Records, and Government Access	Deleted	Sec. 5(h)(1) of the 1937 Act; 2 CFR 200.336; 2 CFR 200.501(g); 24 CFR 905.326; 24 CFR 990.325; 42 USC 1437y and 1437n(e)(C)(4); Sec. 904 of McKinney Homeless Amendments (42 USC 3544); and 5 CFR 5.212(a).
Sec. 10—Grant Funding	Sec. 1—Annual Contributions Terms and Conditions (a.k.a. ACC) (revised and deletes specific information about funding calculations).	24 CFR 905.108 (''Public Housing Requirements'' include ''all applicable federal statutes,'' including appropriations acts); 24 CFR part 905, subpart D (Capital Fund formula); and 24 CFR part 990, subparts B–E (Operating Fund formula).
Sec. 11—Depository	Sec. 7—Depository (no significant deletions)	N/A.
Sec. 12—Termination of a Project	Sec. 10—Termination (no significant deletions)	N/A.
Sec. 13—Notices, Defaults, Remedies	Sec. 9—Substantial Default (deletes notice and possession provisions and deletes mixed-finance provisions).	Sec. 6(j) and Sec. 6(g)(2) of the 1937 Act; and 24 CFR part 907, particularly 24 CFR 907.5 [Mixed-finance provisions will be included in a mixed-finance ACC amendment].
Sec. 14—HUD in Possession of Project(s)	Deleted	Sec. 6(j)(3)(H) of the 1937 Act.
Sec. 15—Conflict of Interest Sec. 17—Members or Delegates to Congress	Sec. 8—Conflict of Interest (deletes procurement conflicts of interest and resident board member requirement).	2 CFR 200.318(c) and Sec. 2(b)(1) of the 1937 Act; 24 CFR part 964, subpart E.
Sec. 18—Rights of Third Parties	Sec. 12—Rights of Third Parties (no deletions)	N/A.
Sec. 19—Waiver or Amendment	Sec. 13—Waiver or Amendment (no significant deletions). Sec. 11—Remedies (did not appear in 60-day notice version of the ACC, therefore no deletions).	N/A. N/A.

Dated: November 5, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

Annual Contributions Terms and Conditions for the Public Housing Program

U.S. Department of Housing and Urban Development

Office of Public and Indian Housing

1. Annual Contributions Terms and Conditions (a.k.a. ACC)—This agreement between the Department of Housing and Urban Development (HUD) and a Public Housing Agency (PHA) establishes HUD's basic terms and conditions for the PHA's federally funded public housing program, and is authorized pursuant to the United States Housing Act of 1937 (the 1937 Act), (42 United States Code (U.S.C.) § 1437 *et seq.*).

a. The ACC includes any funding exhibits, or amendments, to the ACC; and supersedes any previous ACC, or consolidated contributions agreement for the public housing program.

b. The ACC together with the PHA's written submissions for public housing funds including but not limited to, the SF–424 (or successor document) and any exhibits to the SF–424 reflecting HUD's commitment to provide such financial assistance, constitutes a federal award which is not awarded under the Federal Acquisition Regulations.

c. Public housing funds are federal financial assistance provided to a PHA pursuant to the 1937 Act for the development or operation of public housing and include public housing formula funding. Public housing formula funding is provided as non-competitive federal awards for:

- Capital funding provided to a PHA pursuant to section 9(d) (42 U.S.C. 1437g(d) of the 1937 Act (the Public Housing Capital Fund program), and
- operating funding provided to PHAs pursuant to section 9(e) (the Public Housing Operating Fund program) (42 U.S.C. 1437g(e)) of the 1937 Act.

d. The terms ''federal award'' ''federal financial assistance'' and ''recipient'' are defined in 2 Code of Federal Regulations (CFR) (Version 2018) at §§ 200.38, 200.40(a)(1), and 200.86 respectively.

2. Public Housing Administration. The PHA shall administer its public housing program for the provision of decent, safe, and sanitary housing to eligible families in accordance with this agreement and Public Housing Requirements. The PHA shall comply with, and shall ensure compliance by, any contractors or subcontractors with, the Public Housing Requirements.

a. Public Housing Requirements include but are not limited to:

- The 1937 Act as it exists now and as it may be amended in the future;
- Regulations issued by HUD at Title 24 of the CFR and the Uniform Guidance at 2 CFR part 200 as they exist now and as they may be amended in the future;
- Appropriations acts, as they exist now and amended in the future; and
- Other federal statutes, regulations and executive orders applicable to Public Housing Funds and Public Housing Projects; as they exist now and as they may be amended in the future.

b. Nothing herein shall release the PHA from compliance with all applicable laws, executive orders, and regulations (as they exist now or are amended in the future) applicable to the receipt, use, and maintenance of public housing funds and public housing projects that are not specifically incorporated herein by reference. The term ''public housing project'' is defined in 24 CFR 905.108.

3. Encumbrances. Except for dwelling leases with eligible families for public housing dwelling units and normal uses associated with the operation of dwelling units, the PHA shall not encumber (including the pledge as collateral for a loan) a public housing project or portion thereof, public housing funds, or other public housing assets without the prior written approval of HUD.

4. Restrictive Covenants. Promptly upon the PHA's acquisition, development, or assistance of any real property with public housing funds, the PHA shall, consistent with Public Housing Requirements, execute, file for record (prior to the recordation of any other encumbrance), and maintain an instrument against the property (which may be in the form of a declaration of trust, declaration of restrictive covenant, or such other document), as approved or prescribed by HUD.

5. Insurance Requirements. Consistent with 24 CFR 965.205 the PHA shall procure adequate insurance to protect the PHA from financial loss resulting from various hazards.

a. *Mandatory Insurance Coverage.* The following types of insurance are required:

1. Commercial Property. Each policy must be written with a blanket limit, on a replacement cost basis, and with an agreed value clause eliminating any coinsurance provision.

2. Commercial General Liability.

3. Workers Compensation and Employers Liability.

4. Owned and Non-Owned Automobile Liability.

5. Theft, Disappearance, and Destruction, only if the amount of cash and checks on hand at any one time exceeds the amount prescribed by HUD.

6. Employee Dishonesty.

7. Boiler and Machinery only if steam boilers have been installed.

8. Flood Insurance for property located in a flood plain, as determined in the Federal Government's National Flood Insurance Program.

9. Lead-Based Paint Liability for PHAs undergoing lead-based paint testing and abatement.

b. *Optional Insurance Coverage.* Subject to the Cost Principles of the Uniform Guidance, the following insurance coverage is recommended and can be purchased if the PHA determines that exposure exists:

1. Boiler and Machinery coverage is recommended if there is extensive central, conditioning, electrical transformers, or similar equipment.

2. Directors and Officers or Public Officials Liability.

3. Law Enforcement Liability: Highly recommended where the exposure exists, and the Commercial General Liability insurer has excluded coverage.

4. Fidelity Bond Coverage. The PHA is recommended to carry adequate fidelity bond coverage, as required by HUD, of its officers, agents, or employees handling cash or authorized to sign checks.

c. *Authorized Insurance Companies.* Insurance must be purchased from an insurance company or other entity that is licensed or duly authorized to write insurance in the State where the PHA is located. At each renewal, the PHA shall promptly have certificates of insurance submitted by the insurers to HUD describing the types of coverage, limits of insurance, policy numbers, and inception and expiration dates.

d. *Waivers.* Requests for waivers of this section not to purchase any form of required insurance, must be submitted in writing to HUD for approval and include specific justification and risk analysis.

e. *Restoration*—Unless the PHA received prior written approval of HUD to the contrary, the PHA shall, to the extent that insurance proceeds permit, promptly restore, reconstruct, and/or repair any damaged or destroyed Public Housing Project, in accordance with all Public Housing Requirements.

6. Civil Rights and Employer Requirements. Nothing herein shall release the PHA from compliance with all applicable civil rights laws, executive orders, and regulations applicable to the receipt, use, and maintenance of Public Housing Funds; and the operation and development of Public Housing Projects, that are not specifically incorporated herein by reference. The PHA shall comply with all State and Federal laws applicable to employee benefit plans and other conditions of employment.

7. Depository. The PHA shall deposit and invest its public housing funds received by, or held for the account of, the PHA in connection with the development, operation, improvement, and disposition of its Public Housing Project in accordance with the terms of a General Depository Agreement (GDA). The GDA shall be in the form prescribed by HUD and must be executed by the PHA and the depository.

a. Immediately upon the execution of a GDA, the PHA shall furnish to HUD an executed or conformed copy thereof as HUD may require. A GDA shall not be terminated except after 30 days' prior notice to HUD.

b. The PHA shall maintain records that identify the source and application of funds in such a manner as to allow HUD to determine that all funds are and have been expended in accordance with Public Housing Requirements. Except as approved by HUD, and consistent with Public Housing Requirements, funds provided as separate federal awards are not fungible.

8. Conflict of Interest. In addition to any Uniform Guidance conflict of interest requirements at 2 CFR Subpart D, PHAs are subject to the following conflict of interest requirements:

a. Neither the PHA nor any of its contractors or subcontractors may enter into any contract or arrangement, including employment contracts or arrangements, in connection with the operation and administration of the public housing program in which any of the following classes of persons has any real or apparent interest, (direct or indirect), during his or her tenure or for one year thereafter:

1. Any present or former member or officer of the PHA (except a present tenant commissioner who does not serve on the governing body of a resident corporation, and who does not occupy a policymaking position with the resident corporation, the PHA or a business entity), or any member of the officer's immediate family;

2. Any employee of the PHA, or any contractor, subcontractor or agent of the PHA, who formulates policy or who influences decisions with respect to the programs, or any member of the employee's immediate family;

3. Any public official, member of a governing body, or State or local legislator, who exercises functions or responsibilities with respect to the programs, or any member of such individual's immediate family; or

4. Any member of the Congress of the United States; or resident commissioner. As used in this section, the term ''resident commissioner'' refers to an individual appointed to oversee a territory or possession of the United States of America, (*e.g.,* Guam).

b. The officers, employees, and agents of the PHA shall neither solicit nor accept gratuities, favors or anything of monetary value from residents of public housing or participants in programs covered by this agreement; nor enter into any financial arrangement (direct or indirect) with public housing residents or participants in program covered by this agreement. However, the PHA may set written standards for situations in which a gift is an unsolicited item of nominal value.

c. Any member of the classes described in paragraph (a) of this section must disclose their interest or prospective interest to the PHA and HUD.

d. The conflict of interest prohibition under this section may be waived by HUD for good cause if HUD is provided with written evidence that (1) a prohibited contract or arrangement is permitted under State and local law; and (2) the PHA Board of Commissioners supports the waiver.

e. No Public Housing Funds may be used to pay any compensation for the services of members of the PHA's Board of Commissioners.

f. For purposes of this section and the Uniform Guidance (or any succeeding requirements thereto) the term ''immediate family member'' means: spouse, domestic partner, mother, father, mother-in-law, father-in-law, brother, sister, brother-in-law, or sister-in-law, or child of a covered class member (whether related as a full blood relative, or as a ''half'' or ''step'' relative, *e.g.,* a half-brother or stepchild).

9. Substantial Default. Upon the occurrence of a substantial default by the PHA, as determined by HUD, the PHA shall (1) convey to HUD title to the Project(s), or (2) deliver possession and control of the Project(s) to HUD if, in the determination of HUD (which determination shall be final and conclusive), such conveyance or possession is necessary to achieve the purposes of the 1937 Act. HUD shall also be entitled to any or all other remedies allowed by the Public Housing Requirements. A substantial default is a serious and material violation of any one or more of the covenants contained in this agreement, or as defined in the Public Housing Requirements.

a. Events of substantial default under this agreement shall include, but shall not be limited to any of the following occurrences: (1) PHA's failure to maintain and operate the Public Housing Project in a decent, safe, and sanitary manner; (2) PHA's encumbrance of any Public Housing Project or portion thereof without HUD approval; (3) abandonment of any Public Housing Project or assets by the PHA, (4) the determination by HUD that the powers of the PHA to operate the public housing program in accordance with the provisions of this agreement or the Public Housing Requirements are curtailed or limited to an extent that will prevent the accomplishment of the objectives of this Agreement.

b. Nothing contained in this agreement shall prohibit or limit HUD exercising any other right or remedy existing under applicable law, or available at equity. HUD's exercise or non-exercise of any right or remedy under this agreement shall not be construed as a waiver of HUD's right to exercise that or any other right or remedy at any time.

10. Termination. If a Public Housing Project is disposed of (through sale or other method), all related public housing funds shall (in accordance with Public Housing Requirements) become part of another Public Housing Project administered by the PHA. If no other Public Housing Project exists, the remaining personal and real property (including any funds held under or required to be held under a GDA) shall be distributed as directed by HUD, consistent with Public Housing Requirements, which may include remittance to HUD.

11. Breach. This agreement does not contemplate money damages as a remedy for a breach of the agreement by HUD.

12. Rights of Third Parties. Nothing in this agreement shall be construed as creating any right of any third party to enforce any provision of this agreement, or to assert any claim against HUD or the PHA.

13. Waiver or Amendment. The PHA may request a waiver or amendment to this ACC. Any administrative right that HUD may have under this ACC may be waived in writing by HUD for good cause.

Name: _____

Signature and Title: _____

Date: _____

Department of Housing and Urban Development

PHA Acceptance: The PHA hereby accepts this agreement executed by the Department of Housing and Urban Development on the above date as a Recipient designated to receive federal financial assistance for public housing, and agrees to comply with the terms and conditions of this agreement, applicable Public Housing Requirements, and other requirements of HUD now or hereafter in effect, pertaining to the federal financial assistance provided the PHA for its public housing program.

Name: _____

Signature and Title: _____

Date: _____

Public Housing Agency

Mixed-Finance Amendment

To the Annual Contributions Terms and Conditions for the Public Housing Program (ACC)

I. On _____ the United States Department of Housing and Urban Development (''HUD'') and _____ (''PHA'') executed an Annual Contributions Terms and Conditions for the Public Housing Program (''ACC''), which establishes HUD's basic terms and conditions for the PHA's federally funded public housing grant programs.

II. This Mixed-Finance Amendment to the ACC (''Mixed-Finance Amendment'') sets forth additional requirements that apply to the public housing units and related appurtenances (''Project Units'' or ''Project''), which are being developed as part of the larger development known as _____ (the ''Development''), for which HUD approved a development proposal and related evidentiary documents (together known as the ''Development Proposal'') on _____.

III. The following amendments are made to the ACC and shall apply to the Project Units and/or Project, unless otherwise approved by HUD.

A. *Section 3, Encumbrances:* The requirements of Section 3 of the ACC are replaced with the following requirements:

1. Neither the Project Units nor any part thereof shall be demolished or disposed of, encumbered in any way, or the assets of the Project pledged as collateral for a loan, other than in accordance with the terms of the Public Housing Requirements and only with prior written approval of HUD, so long as this Mixed-Finance Amendment

remains in force with respect to the Project, with the exception of:

a. Mortgage, deeds of trust, and other financing arrangements approved as part of the Development Proposal;

b. Dwelling leases with eligible families living in the Project;

c. Conveyance or dedication of land for use as streets, alleys, or other public rights-of-way, and grants and easements for the establishment, operation and maintenance of public utilities approved as part of the Development Proposal;

d. A memorandum of ground lease for record against the Project prior to recordation of the HUD restrictive covenant, as approved by HUD as part of the Development Proposal; and,

e. Normal uses associated with operation of the Project.

2. No transfer, conveyance, or assignment of the Project shall be made without the prior written approval of HUD of:

a. Any interest of a managing member, general partner, or controlling stockholder (any such interest being referred to as a ''Controlling Interest'') of the Owner; or

b. a Controlling Interest in any entity which has a Controlling Interest in the Owner; or

c. any other interest in the Owner, or in any partner or member thereof, prior to the payment in full of all equity contributions, as approved in the Development Proposal.

3. Notwithstanding the foregoing, HUD consent is not required where a business organization that has a limited interest (non-controlling and non-managing) in the Owner transfers a non-controlling and non-managing interest in the business organization, provided that the Owner:

a. Provides HUD with written notice of such transfer; and

b. certifies to HUD that the new owner of the limited interest remains obligated to fund its equity contribution in accordance with the terms of the organizational documents of the Owner.

4. Notwithstanding the foregoing, the prior approval of HUD shall not be required for the exercise by the investor, *i.e.,* limited partner, limited owner, etc. or its affiliates (''Limited Interest''), of their rights to remove a Controlling Interest of the Owner or partner or member thereof and to designate an affiliate of the Limited Interest as a substitute Controlling Interest under the terms of the Partnership Agreement or Operating Agreement, provided that HUD is given prior written notice of default and of the Limited Interest's intent to exercise its right of removal and appointment under the Partnership Agreement or Operating Agreement (the ''Notice''). *However,* HUD consent shall be required for the appointment of any permanent replacement Controlling Interest or substitute Controlling Interest beyond a 90-day period. Such 90-day period will commence on the date of the Notice (the ''Interim Replacement Period''). With notice and the prior written approval of HUD, the Interim Replacement Period may be extended for an additional 90 days to allow the Limited Interest to find a permanent replacement Controlling Interest acceptable to HUD, provided that prior to the expiration of such additional 90-day period, the substitute Controlling Interest demonstrates that the Limited Interest is continuing to fund (or has already funded) its equity contribution, as required under the Partnership Agreement or Operating Agreement, and that the Project continues to be operated in a manner consistent with the Public Housing Requirements.

5. HUD and the PHA authorize a Controlling Interest to collaterally assign and pledge its interest in the Owner to a construction and/or permanent lender, and to allow a construction and/or permanent lender to exercise any of its rights pursuant thereto, so long as the construction and/or permanent lender gives prompt written notice to HUD at the time it exercises such rights (the ''*Pledge Notice*''). However, consent of HUD shall be required for the appointment of any permanent replacement Controlling Interest or substitute Controlling Interest (including construction and/or permanent lender or its Affiliates) extending beyond a 90-day period. Such 90-day period will commence on the date of the Pledge Notice (the ''*Pledge Replacement Period*''). With notice to the PHA and notice and prior written consent of HUD, the Pledge Replacement Period may be extended for an additional 90 days to allow construction and/or permanent lender to find a permanent replacement Controlling Interest acceptable to HUD and the PHA, provided that prior to the expiration of such additional 90-day period, the substitute Controlling Interest demonstrates that the Limited Interest is continuing to fund (or has already funded) its equity contribution as required by the Owner's Partnership Agreement (or, if the Owner is a limited liability company, the Owner's Operating Agreement) and that Project continues to be operated in accordance with the Public Housing Requirements.

6. HUD will not unreasonably withhold, delay, or condition a request by the Owner for HUD's consent to an internal reorganization of the corporate or partnership structure of the Owner or any of the partners, members or stockholders of the Owner.

B. *Section 4, Restrictive Covenants:* The requirements of Section 4 of the ACC are replaced with the following requirements:

1. The PHA shall require the Owner to execute and file on record against the Development, in the order approved by HUD, an instrument against the property (which may be in the form of a declaration of trust, declaration of restrictive covenants, or such other document as approved or prescribed by HUD) that encumbers the property and confirms the Owner's obligation to develop, maintain and operate the Project in compliance with the Public Housing Requirements. This instrument may not be modified, amended or released without the prior written approval of HUD.

C. *Section 5(e), Restoration:* The requirements of Section 5(e) of the ACC are replaced with the following requirements:

1. Taking or Casualty: In the event of a taking or threatened taking by condemnation or other exercise of eminent domain of all or a portion of the Development (collectively a ''Taking'') or the occurrence of a fire or other casualty resulting in damage to all or a portion of the Development (collectively a ''Casualty''), the following shall apply:

The PHA shall promptly cause the restoration, reconstruction, and/or repair (''Restoration'') of any damaged or destroyed property of the Development, but only to the extent that insurance proceeds or condemnation award proceeds (''Proceeds'') permit and only if Restoration is feasible. The obligation for Restoration, to the extent Proceeds and other funds (if any are made available by the Owner or the PHA) permit, is also a requirement with which the Owner must comply, if Restoration is feasible. In addition, each mortgagee must permit Restoration if Proceeds permit and if Restoration is feasible (rather than require application of Proceeds to reduce mortgage debt.)

Restoration is deemed ''feasible'' if (without limitation), following Restoration, the financial viability of the Project would not be materially impaired from its condition prior to the casualty, including (without limitation) if tax benefits would not be materially reduced or if committed sources of debt or equity financing would not be relieved of their obligation to fund as a result of the Casualty.

However, a mortgage may provide and a mortgagee may exercise (with HUD approval, as provided below), an option

to apply any Proceeds to repayment of the mortgage debt instead of restoration, if any of the following conditions is met in the reasonable determination of the mortgagee or, if different, the lender:

a. There is no substantial certainty of sufficient funds for Restoration (whether from insurance proceeds, a condemnation award or settlement, or other funds that may be provided by the Owner, the PHA or other lenders);

b. there is no substantial certainty that Restoration will be completed prior to the maturity date of the note secured by the mortgage;

c. if the loan is a construction loan, there is no substantial certainty that committed and sufficient loan repayment sources will be available upon Restoration, completion and loan maturity;

d. there is no substantial certainty that the operating income of the Development following Restoration will be sufficient to meet all operating costs and other expenses, payments for reserves, and loan repayment obligations relating to the Development;

e. there is no substantial certainty that Restoration of the Development to a condition approved by lender will be completed prior to the earlier of the maturity date of the loan or any fixed date resulting from tax credit requirements or otherwise imposed by schedule sources of repayment for the loan.

2. Restoration Is Not Feasible: In the event a lender, Owner and/or PHA determines that Restoration is not feasible, the PHA shall apply to HUD for approval not to restore the Project, which shall not be unreasonably withheld, conditioned or delayed. Upon HUD approval not to restore the project, Proceeds shall be applied as follows:

a. To pay-off or reduce outstanding mortgage debt in accordance with the recordation order of the mortgage liens on the Development;

b. to reduce any outstanding indebtedness of the Owner to the PHA for an unsecured loan;

c. to reimburse the PHA for any funds disbursed to the Owner for development of the Development other than by loan. Such reimbursement shall include any funds provided by the PHA for predevelopment work or soft costs;

d. to the Owner, in an amount equal to the amount that the Owner or its general partner or managing member is required to pay to any investor member or partner in connection with the Casualty or Taking, as provided for in the Owner's limited partnership agreement or operating agreement, such as repurchase of an interest, the triggering of ''credit adjusters'', or otherwise;

e. to the Owner, to the extent not otherwise covered by paragraph (d), above, in an amount equal to the amount that the Owner is required to pay or distribute upon dissolution in accordance with its limited partnership agreement or operating agreement, including without limitation all debts of the Owner whether to third persons or to partners or members, and whether for funds advanced, property or services, but disregarding for this purpose any provision in the limited partnership agreement or operating agreement for distribution of residual funds.

f. to the PHA an amount equal to the total ''cost of construction'' attributable to the Project Units, less the sum of (a), (b) and (c) above; and,

g. to the Owner Entity.

3. Restoration Is Feasible—Partial Loss: In the event lender, Owner Entity and/or PHA determine that Restoration is feasible and less than all of the dwelling units in the Development are damaged, destroyed or lost as a result of casualty or condemnation, the following provisions shall apply:

a. If the Proceeds are sufficient to restore the Development to the same number of units that existed prior to the Casualty or Taking, the number of Project Units in the Development shall be the same number (and bedroom configuration) that existed prior to the Casualty or Taking.

b. If the Proceeds are not sufficient to restore the Development to the same number of units that existed prior to the Casualty or Taking, the number of Project Units in the Development shall be the same percentage of the total number of units (and bedroom configuration) as existed prior to the Casualty or Taking.

c. Any excess Proceeds remaining following redevelopment shall be distributed as follows:

i. To pay-off or reduce outstanding mortgage debt in accordance with the recordation order of the mortgage liens on the Development;

ii. to reduce any outstanding indebtedness of the Owner to the PHA for an unsecured loan;

iii. to reimburse the PHA for any funds disbursed to the Owner Entity for development of the Development other than by loan. Such reimbursement shall include any funds provided by the PHA for predevelopment work or soft costs;

iv. to the Owner, in an amount equal to the amount that the Owner or its general partner or managing member is required to pay to any investor member or partner in connection with the Casualty or Taking, as provided for in the Owner's limited partnership agreement or operating agreement, such as repurchase of an interest, the triggering of ''credit adjusters'', or otherwise;

v. to the Owner, to the extent not otherwise covered by paragraph (iii), above, in an amount equal to the amount that the Owner is required to pay or distribute upon dissolution in accordance with its limited partnership agreement or operating agreement, including without limitation all debts of the Owner whether to third persons or to partners or members, and whether for funds advanced, property or services, but disregarding for this purpose any provision in the limited partnership agreement or operating agreement for distribution of residual funds;

vi. to the PHA an amount equal to the total ''cost of construction'' attributable to the Project Units, less the sum of (i), (ii) and (iii), above; and,

vii. to the Owner.

4. Restoration is Feasible—Total Loss: In the event that all of the units in the Project are damaged, destroyed or lost as a result of casualty or condemnation, and lender, Owner and/or PHA determine that restoration is feasible, the following provisions shall apply:

a. If the Proceeds are sufficient to restore the Development to the same number of units that existed prior to the Casualty or Taking, the number of Project Units in the Development shall be the same number (and bedroom configuration) that existed prior to the Casualty or Taking.

b. If the Proceeds are not sufficient to restore the Development to the same number of units that existed prior to the Casualty or Taking, the number of Project Units in the Development shall be the same percentage of the total number of units (and bedroom configuration) as existed prior to the Casualty or Taking.

c. Any excess Proceeds remaining following redevelopment, shall be distributed as follows:

i. To pay-off or reduce outstanding mortgage debt in accordance with the recordation order of the mortgage liens on the Development;

ii. to reduce any outstanding indebtedness of the Owner Entity to the PHA for an unsecured loan;

iii. to reimburse the PHA for any funds disbursed to the Owner Entity for development of the Development other than by loan. Such reimbursement shall include any funds provided by the PHA for predevelopment work or soft costs;

iv. to the Owner, in an amount equal to the amount that the Owner or its general partner or managing member is required to pay to any investor member

or partner in connection with the Casualty or Taking, as provided for in the Owner's limited partnership agreement or operating agreement, such as repurchase of an interest, the triggering of ''credit adjusters'', or otherwise;

v. to the Owner, to the extent not otherwise covered by paragraph (iii), above, in an amount equal to the amount that the Owner is required to pay or distribute upon dissolution in accordance with its limited partnership agreement or operating agreement, including without limitation all debts of the Owner whether to third persons or to partners or members, and whether for funds advanced, property or services, but disregarding for this purpose any provision in the limited partnership agreement or operating agreement for distribution of residual funds;

vi. to the PHA an amount equal to the total ''cost of construction'' attributable to the Project Units, less the sum of (i), (ii) and (iii), above; and,

vii. to the Owner.

5. The term ''cost of construction'' shall mean the total cost of developing the Development, less land acquisition costs, if any, included as part of the initial development budget.

6. The above restoration requirements must be incorporated into or otherwise addressed by the Regulatory and Operating Agreement between the PHA and the Owner (and ground lease, if applicable) and all mortgage documents encumbering the Development shall be consistent with these provisions.

D. *Section 9, Substantial Default:* In addition to the requirements of Section 9 of the ACC, the following shall constitute an event of substantial default under the ACC:

1. The drawdown and/or expenditure of Public Housing Funds is in an amount greater than approved in the Development Proposal or in an amount greater than allowed by the Public Housing Requirements;

2. a serious and material breach of any provision of the Development Proposal; and,

3. a serious and material breach of any terms, covenants, agreements, provisions, or warranties of:

a. The PHA, which in the opinion of HUD, adversely affects the performance obligations of the PHA, the Owner, and/or other participating parties; and

b. the Owner, partner, or other participating party, made in any agreement or document submitted to HUD as part of the Development Proposal, which, in the opinion of HUD, adversely affects the performance obligations of the PHA, the Owner, partner, and/or other participating parties.

4. HUD shall permit an Owner, partner, or lender to participate, and may in its discretion, permit any other party to the Development to participate in any appeal from a notice of substantial default delivered by HUD to the PHA pursuant to this Mixed-Finance Amendment or the Public Housing Requirements, with respect to the Project.

5. During the term of any agreement between the PHA and Owner, and so long as the Owner shall not be in default of its obligations thereunder, HUD agrees that in the event of the substantial default by the PHA under this Mixed-Finance Amendment, HUD shall exercise any remedies or sanctions authorized by the ACC and this Mixed-Finance Amendment or the Public Housing Requirements, including taking possession of the PHA's interest in the Project, in such a manner as not to disturb the Owner's rights under any such agreements.

6. Any rights of the mortgagee under a Note and First Mortgage (if any), including the right to exercise all remedies specified therein, shall not be subordinate to any other obligations imposed upon the Project, except as such obligations (a) shall be reflected in the HUD restrictive covenant approved by HUD, as provided for in Paragraph B of this Mixed-Finance Amendment, or a memorandum of lease (if applicable), and/or any other recorded instrument which shall have been recorded prior to the lien of the First Mortgage or (b) shall be the subject of a subordination agreement with such mortgagee.

IV. *Terms and Conditions:* All other terms and conditions of the ACC shall remain applicable to the Project, unless otherwise waived or amended by HUD.

[Signature on the Following Page]

In consideration of the foregoing covenants, the parties do hereby execute this Mixed-Finance ACC Amendment:

Housing Authority

By: _____

(signature)

Name: _____

Title: _____

United States of America

Secretary of Housing and Urban Development

By: _____

(signature)

Name: _____

Title: _____

Date: _____

[FR Doc. 2019–24426 Filed 11–7–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7016–N–03]

60-Day Notice of Proposed Information Collection: License for the Use of Personally Identifiable Information Protected Under the Privacy Act of 1974

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development (HUD) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 7, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5534 (this is not a toll-free number) or by email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–5000; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the

proposed collection of information described in Section A.

A. Overview of Information Collection

Title of Information Collection: License for the Use of Personally Identifiable Information Protected Under the Privacy Act of 1974.

OMB Approval Number: 2528–0297.

Type of Request: Revision of a currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The United States Department of Housing and Urban Development (HUD) collects and maintains personally identifiable information on tenants in public and assisted housing, the confidentiality of which is protected by the Privacy Act of 1974 (5 U.S.C. 552a). On occasion, HUD shares this information with researchers subject to stringent requirements to protect these households from unauthorized disclosure of information. The purpose for sharing is to further policy-relevant research on the effectiveness of HUD programs.

HUD may, under the terms of its Routine Use Inventory (77 FR 17361), share these data with researchers whom HUD has awarded contracts, grants, or service agreements. HUD has shared data with contractors and grantees and will continue to share data under service agreements because it has a legal form for effectuating such an agreement. HUD does not limit access to the information to parties that have received specific funding to carry out a study through a grant or contract. Instead, HUD also shares the data with legitimate research organizations that have conceived policy-relevant analyses and that are able and willing to protect the data from unauthorized disclosure. The legal form for the service agreement is herein called a ''license.''

HUD will continue making the data available for statistical, research, or evaluation purposes to organizations qualified and capable of research and analysis consistent with the statistical, research, or evaluation purposes for which the data were provided or are maintained, but only if the data are used and protected in accordance with the terms and condition stated in the license, upon receipt of such assurance of qualification and capability, and it is agreed by the organization requesting such information and HUD.

Members of affected public: Individuals in a research capacity of an organization or academic institution.

Estimated Number of Respondents: 15.

Estimated Time per Response: 1 hour.

Frequency of Response: Once annually.

Estimated Total Annual Burden Hours: 106 hours.

Estimated Total Annual Cost: The total estimated cost is $3,710.00.

Respondent's Obligation: Voluntary.

Legal Authority: This application form is conducted under Title 12, U.S.C., Section 1701z–1 *et seq.*

Respondents (i.e., affected public): Organizations.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Applicants	15	1	15	1	15	$50.00	$750.00
Quarterly Reports	0	0	0	0	0	0	0
Annual Reports	40	1	40	1	40	44.00	1,760.00
Final Reports	6	1	6	1	6	50.00	300.00
Recordkeeping	15	3	45	1	45	20.00	900.00
Total Burden Hours	76				106		3,710.00

B. Solicitation of Public Comment

This notice solicits comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 28, 2019.

Seth D. Appleton,

Assistant Secretary for Policy Development and Research.

[FR Doc. 2019–24431 Filed 11–7–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2019–N142; FXES11130300000–190–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application for a permit to conduct activities intended to enhance the propagation or survival of an endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on this application. Before issuing the requested permit, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before December 9, 2019.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the application and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant's name and application number (TE53584D):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective application number TE53584D in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife

Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, 612–713–5343 (phone); *permitsR3ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Application Available for Review and Comment

We invite local, State, and Federal agencies, Tribes, and the public to comment on the following application.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE53584D	U.S. Geological Survey Columbia Environmental Research Center, Columbia, MO.	Spectaclecase mussel (*Cumberlandia monodonta*).	Missouri ...	Conduct presence/absence surveys, document habitat use, conduct scientific research and population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue a permit to the applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services, Region 3.

[FR Doc. 2019–24387 Filed 11–7–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[120D0102DR/DS5A300000/DR.5A311.IA000118]

Land Acquisitions; Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary—Indian Affairs made a final agency determination to acquire 13.3 acres, more or less, of land in trust for the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California, for gaming and other purposes on October 7, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Bureau of Indian Affairs, MS–3657 MIB, 1849 C Street NW, Washington, DC 202240, telephone (202) 219–4066.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 Departmental Manual 8.1, and is published to comply with the requirements of 25 CFR 151.12(c)(2)(ii) that notice of the decision to acquire land in trust be promptly provided in the **Federal Register**.

On October 7, 2019 the Assistant Secretary—Indian Affairs made a final agency determination to transfer the Section 33 Parcel consisting of approximately 13.3 acres, more or less, into trust for the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California (Tribe), pursuant to the Indian Reorganization Act of 1934, 25 U.S.C. 5108. The Assistant Secretary—Indian Affairs also determined that the Tribe's request also meets the requirements of the Indian Gaming Regulatory Act's ''contiguous lands'' exception, 25 U.S.C. 2719(b)(1)(a), to the general prohibition contained in 25 U.S.C. 2719(a) on gaming on lands acquired in trust after October 17, 1988.

The Assistant Secretary—Indian Affairs, on behalf of the Secretary of the Interior, will immediately acquire title to the Section 33 Parcel, in the name of the United States of America in Trust for the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California, upon fulfillment of Departmental requirements. The 13.3 acres, more or less, are described as follows:

Legal Description of Property

Correction No. 2 to Grant Deed recorded May 31, 2019 as Instrument No. 2019–0195673 of Official Records.

PARCEL 1: (APN: 687–202–022)

LOT 49 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPTING THEREFROM, THAT PORTION DESCRIBED IN DEED TO THE COUNTY OF RIVERSIDE, RECORDED ON JANUARY 15, 1973, AS INSTRUMENT NO. 5715 OF OFFICIAL RECORDS.

PARCEL 2: (APN: 687–208–027 and –028)

LOTS 95, 96, 97, 98, 99 AND 100 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND

26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

TOGETHER WITH THAT PORTION OF 20.00 FOOT ALLEY, VACATED AND CLOSED TO PUBLIC USE BY RESOLUTION NO. 79–346, OF THE COUNTY OF RIVERSIDE, RECORDED NOVEMBER 21, 1979 AS INSTRUMENT NO. 248832 OF OFFICIAL RECORDS.

EXCEPTING THEREFROM, THAT PORTION DESCRIBED IN DEED TO THE CITY OF CATHEDRAL CITY, RECORDED OCTOBER 30, 1997 AS INSTRUMENT NO. 395119 OF OFFICIAL RECORDS, AND EXCEPTING THAT PORTION DESCRIBED IN DEED TO THE COUNTY OF RIVERSIDE, RECORDED MAY 18, 1977 AS INSTRUMENT NO. 89251 OF OFFICIAL RECORDS.

PARCEL 3: (APN: 687–201–012)

THE WEST 50.00 FEET OF THE EAST 100.00 FEET OF THE NORTH HALF OF LOT 45 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 4: (APN: 687–201–013)

THE EAST 50.00 FEET OF THE NORTH 87.50 FEET OF LOT 45 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 5: (APN: 687–201–007)

THE SOUTH 87.50 FEET OF THE EAST 100 FEET OF LOT 45 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 6: (APN: 687–201–014)

THE NORTH 87.50 FEET OF THE WEST 50.00 FEET OF LOT 46 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 7: (APN: 687–201–015)

THE EAST HALF OF THE NORTHWEST QUARTER OF LOT 46 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 8: (APN: 687–201–010)

THE SOUTHWEST QUARTER OF LOT 46 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26, OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 9: (APN: 687–201–016)

THE EAST 100.00 FEET OF LOT 46 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 10: (APN: 687–202–016)

THE WESTERLY 85.00 FEET OF THE NORTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 11: (APN: 687–202–002)

THE WEST 85.00 FEET OF THE NORTH HALF OF THE SOUTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 12: (APN: 687–202–003)

THE WESTERLY 85.00 FEET OF THE SOUTH HALF OF THE SOUTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 13: (APN: 687–202–017)

THE WESTERLY 55.00 FEET OF THE EAST 115.00 FEET OF THE NORTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 14: (APN: 687–202–005)

THE SOUTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26, OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPT THE WESTERLY 85.00 FEET THEREOF AND ALSO EXCEPT THE EASTERLY 50.00 FEET THEREOF.

PARCEL 15: (APN: 687–202–018)

THE EAST 60.00 FEET OF THE NORTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 16: (APN: 687–202–007)

THE EAST 50.00 FEET OF SOUTH HALF OF LOT 47 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 17: (APN: 687–202–019)

THE WEST 40.00 FEET OF THE NORTH HALF OF LOT 48 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 18: (APN: 687–202–009)

THE WEST 50.00 FEET OF THE SOUTH 87.50 FEET OF LOT 48 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS·OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 19: (APN: PORTION 687–202–020)

THE EAST 60.00 FEET OF THE WEST 100.00 FEET OF THE NORTH HALF OF LOT 48 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 20: (APN: PORTION 687–202–020)

THE NORTH 8.50 FEET OF THE EAST 50.00 FEET OF THE SOUTH 87.50 FEET OF THE WEST 100.00 FEET OF LOT 48 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 21: (APN: 687–202–011)

THE EAST 50.00 FEET OF THE SOUTH 79.00 FEET OF THE WEST 100.00 FEET OF LOT 48 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 22: (APN: 687–202–021)

THE EAST 100.00 FEET OF LOT 48 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 23: (APN: 687–203–008)

THE NORTH HALF OF LOT 66 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 24: (APN: 687–203–009)

THE SOUTH HALF OF LOT 66 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 25: (APN: 687–203–010)

LOT 65 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 26: (APN: 687–203–011)

LOT 64 OF CATHEDRAL CITY AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 27: (APN: 687–203–012)

THE NORTH HALF OF LOT 63 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 28: (APN: 687–203–013)

THE SOUTH HALF OF LOT 63 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 29: (APN: 687–203–014)

LOT 62 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 30: (APN: 687–203–015)

THE NORTH 65.00 FEET OF LOT 67 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 31: (APN: 687–204–001)

LOT 61 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13,

PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 32: (APN: 687–204–002)

THE NORTH 85.00 FEET OF LOT 60 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 33: (APN: 687–204–003)

THE SOUTH 65.00 FEET OF LOT 60 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 34: (APN: 687–204–004)

THE NORTH HALF OF LOT 59 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 35: (APN: 687–204–005)

THE SOUTH HALF OF LOT 59 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 36: (APN: 687–204–006)

THE NORTH HALF OF LOT 58 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 37: (APN: 687–204–007)

THE SOUTH HALF OF LOT 58 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 38: (APN: 687–204–008 and –013)

THE NORTH HALF OF LOTS 56 AND 57 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

TOGETHER WITH THE WESTERLY HALF OF THE ALLEY ADJOINING SAID LOT 56 ON THE EAST AS VACATED AND CLOSED TO PUBLIC USE BY RESOLUTION NO. 80–367, RECORDED OCTOBER 23, 1980 AS INSTRUMENT NO. 197351 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 39: (APN: 687–204–009 and –014)

THE SOUTH HALF OF LOTS 56 AND 57 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

TOGETHER WITH THE WESTERLY HALF OF THE ALLEY ADJOINING SAID LOT 56 ON THE EAST AS VACATED AND CLOSED TO PUBLIC USE BY RESOLUTION NO. 80–367, RECORDED OCTOBER 23, 1980 AS INSTRUMENT NO. 197351 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 40: (APN: 687–204–017)

LOTS 50, 51, 52, 53, 54 AND 55 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

TOGETHER WITH THE EAST HALF OF THAT PORTION OF LOT H (ALLEY) ADJOINING SAID LOT 55 ON THE WEST, VACATED BY THE BOARD OF SUPERVISORS OF THE COUNTY OF RIVERSIDE, RESOLUTION NO. 80–367, RECORDED OCTOBER 23, 1980 AS INSTRUMENT NO. 197351 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 41: (APN: 687–206–001; –002 and –003)

LOT 83, 84 AND 85 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13 PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 42: (APN: 687–206–004)

LOT 86 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 43: (APN: 687–206–005)

THAT PORTION OF LOT 87 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, DESCRIBED AS FOLLOWS:

BEGINNING AT THE NORTHWEST CORNER OF SAID LOT 87; THENCE EAST ON THE NORTH LINE THEREOF, 40.00 FEET; THENCE SOUTH 30.00 FEET; THENCE SOUTHWESTERLY, ON A LINE TO A POINT 20.00 FEET EAST OF THE WEST LINE OF SAID LOT, AND 40.00 FEET SOUTH OF THE NORTH LINE OF SAID LOT; THENCE SOUTH 10.00 FEET; THENCE WEST 20.00 FEET TO THE WEST LINE OF SAID LOT; THENCE NORTH ON THE WEST LINE OF SAID LOT 50.00 FEET TO THE POINT OF BEGINNING.

PARCEL 44: (APN: 687–206–006)

THAT PORTION OF LOTS 87 AND 88 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGE 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, DESCRIBED AS FOLLOWS:

BEGINNING AT THE SOUTHWEST CORNER OF SAID LOT 87; THENCE NORTHERLY ON THE WESTERLY LINE OF SAID LOT, 50.00 FEET, MORE OR LESS, TO THE SOUTHWEST CORNER OF THAT CERTAIN PARCEL OF LAND CONVEYED TO OLIVER D. WENGER, ET UX, IN DEED RECORDED NOVEMBER 4, 1937 IN BOOK 353, PAGE 32 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA; THENCE EASTERLY ON THE SOUTHERLY LINE OF SAID PARCEL CONVEYED TO OLIVER D. WENGER, 20.00 FEET; THENCE NORTHERLY ON THE EASTERLY LINE OF SAID PARCEL, 10.00 FEET; THENCE IN A NORTHEASTERLY DIRECTION, 22.00 FEET, MORE OR LESS, TO A POINT IN THE MOST EASTERLY LINE OF SAID PARCEL CONVEYED TO OLIVER D. WENGER, THAT IS 30.00 FEET SOUTHERLY FROM THE NORTHERLY LINE OF SAID LOT 87, SAID POINT BEING IN THE WESTERLY LINE OF THAT CERTAIN PARCEL OF LAND CONVEYED TO ERNEST NORTH SMITH, IN DEED RECORDED DECEMBER 9, 1947 IN BOOK 878, PAGE 217 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA; THENCE SOUTHERLY ON THE WESTERLY LINE OF SAID PARCEL CONVEYED TO ERNEST NORTH SMITH, 8.00 FEET, MORE OR LESS, TO THE SOUTHWESTERLY CORNER THEREOF; THENCE EASTERLY ON THE SOUTHERLY LINE OF SAID PARCEL CONVEYED TO ERNEST NORTH SMITH, 20.00 FEET, MORE OR LESS, TO THE SOUTHEASTERLY CORNER THEREOF; SAID POINT BEING ON THE WESTERLY LINE OF THAT CERTAIN PARCEL OF LAND CONVEYED TO JOSEPH LAWRENCE, SR., ET UX, IN DEED RECORDED JANUARY 09, 1948 IN BOOK 877, PAGE 549 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY RECORDS, CALIFORNIA; THENCE SOUTHERLY ON THE WESTERLY LINE OF SAID PARCEL CONVEYED TO JOSEPH LAWRENCE, SR., AND THE WESTERLY LINE OF THAT CERTAIN PARCEL OF LAND CONVEYED TO HAROLD A. SMITH A SINGLE MAN, IN DEED RECORDED NOVEMBER 10, 1947 IN BOOK 872, PAGE 386 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, 62.00 FEET, MORE OR LESS, TO A POINT ON THE SOUTHERLY LINE OF SAID LOT 88; THENCE WESTERLY ON THE SOUTHERLY LINE OF SAID LOTS 88 AND 87, 60.00 FEET, MORE OR LESS, TO THE POINT OF BEGINNING.

PARCEL 45: (APN: 687–206–007)

THOSE PORTIONS OF LOTS 87 AND 88 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13 PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY CALIFORNIA, DESCRIBED AS FOLLOWS:

BEGINNING AT THE NORTHEAST CORNER OF LOT 87; THENCE WEST ON THE NORTH LINE OF LOT 87, 10.00 FEET; THENCE SOUTH 38.00 FEET; THENCE EAST 20.00 FEET; THENCE SOUTH 12.00 FEET; THENCE EAST 40.00 FEET TO THE EAST LINE OF LOT 88; THENCE NORTH 50.00 FEET TO THE NORTHEAST CORNER OF LOT 88; THENCE WEST ON THE NORTH LINE OF LOT 88, 50.00 FEET TO THE POINT OF BEGINNING.

PARCEL 46: (APN: 687–206–008)

THE EAST 40.00 FEET OF THE SOUTH 50.00 FEET OF LOT 88 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 47: (APN: 687–206–009 and –010)

LOTS 89 AND 90 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13 PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 48: (APN: 687–206–011)

THE NORTH 58.00 FEET OF LOT 91 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 49: (APN: 687–206–012)

THE SOUTHERLY 42.00 FEET OF LOT 91 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 50: (APN: 687–206–013)

LOT 92 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13 PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 51: (APN: 687–206–014)

THE NORTH 55.00 FEET OF LOT 93 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 52: (APN: 687–206–015)

THE SOUTH 45.00 FEET OF LOT 93 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 53: (APN: 687–206–016)

LOT 94 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13 PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 54:

THOSE PORTIONS OF LOT ''B'' (HILLERY ROAD, FORMERLY FIRST STREET), LOT ''G'' (ALLEN AVENUE), AND LOT ''Y'' (HILLERY ROAD, FORMERLY FIRST STREET), AS SHOWN ON THE MAP OF CATHEDRAL CITY, FILED IN BOOK 13, PAGES 24 THROUGH 26, OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, TOGETHER WITH THOSE CERTAIN ALLEYS LOCATED WITHIN LOTS 45 AND 48 OF SAID CATHEDRAL CITY, AS SHOWN ON SAID MAP, ALL LOCATED WITHIN THE EAST HALF OF SECTION 33, TOWNSHIP 4 SOUTH, RANGE 5 EAST, SAN BERNARDINO MERIDIAN, DESCRIBED AS FOLLOWS:

SEGMENT A:

ALL OF LOT ''B'' (HILLERY ROAD, FORMERLY FIRST STREET), AS SHOWN ON SAID MAP OF CATHEDRAL CITY.

SEGMENT B:

THAT PORTION OF LOT ''G'' (ALLEN AVENUE), AS SHOWN ON SAID MAP, BOUNDED ON THE NORTH BY THE WESTERLY PROLONGATION OF THE SOUTH LINE OF LOT ''A'' (BUDDY ROGERS AVENUE, FORMERLY SECOND STREET), AND BOUNDED ON THE SOUTH BY THE WESTERLY PROLONGATION OF THE NORTH LINE OF LOT ''C'' (GROVE STREET);

SEGMENT C:

THE EAST 300.00 FEET OF LOT ''Y'' (HILLERY ROAD, FORMERLY FIRST STREET), AS SHOWN ON SAID MAP.

SEGMENT D:

THE WEST 20.00 FEET OF THE EAST 120.00 FEET OF LOT 45 AS SHOWN ON THE MAP OF CATHEDRAL CITY, FILED IN BOOK 13, PAGES 24 THROUGH 26, INCLUSIVE, OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, AS SHOWN ON THE MAP FILED IN BOOK 11, PAGE 11 OF RECORDS OF SURVEY, RECORDS OF RIVERSIDE COUNTY.

SEGMENT E:

THE WEST 20.00 FEET OF THE EAST 120.00 FEET OF LOT 48 AS SHOWN ON THE MAP OF CATHEDRAL CITY, FILED IN BOOK 13, PAGES 24 THROUGH 26, INCLUSIVE, OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, AS SHOWN ON THE MAP FILED IN BOOK 11, PAGE 11 OF RECORDS OF SURVEY, RECORDS OF RIVERSIDE COUNTY.

PARCEL 55: (APN: 687–205–009)

LOTS 78 AND 79 OF CATHEDRAL CITY AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPTING THEREFROM, THAT PORTION CONDEMNED TO THE CITY OF CATHEDRAL CITY, AS DISCLOSED BY DOCUMENT RECORDED MARCH 24, 1999 AS INSTRUMENT NO. 99–121245 AND MAY 17, 1999 AS INSTRUMENT NO. 99–212072, BOTH OF OFFICIAL RECORDS, DESCRIBED AS FOLLOWS:

BEGINNING AT THE SOUTHEAST CORNER OF SAID LOT 79; THENCE ALONG THE EAST LINE OF SAID LOT 79, NORTH 00°04′35″ EAST, 6.42 FEET; THENCE NORTH 71°34′43″ WEST, 158.18 FEET TO THE WEST LINE OF SAID LOT 78; THENCE ALONG THE WEST LINE OF SAID LOT 78, SOUTH 00°01′53″ WEST, 6.42 FEET TO THE SOUTHWEST CORNER OF SAID LOT 78; THENCE ALONG THE SOUTH LINE OF SAID LOTS 78 AND 79, SOUTH 71°34′48″ EAST, 158.18 FEET TO SAID SOUTHEAST CORNER AND THE POINT OF BEGINNING.

PARCEL 56: (APN: 687–205–010)

LOT 80 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPTING THEREFROM, THAT PORTION CONDEMNED TO THE CITY OF CATHEDRAL CITY, AS DISCLOSED BY DOCUMENT RECORDED MARCH 24, 1999 AS INSTRUMENT NO. 99–121245 AND RECORDED MAY 17, 1999 AS INSTRUMENT NO. 212072, BOTH OF OFFICIAL RECORDS, DESCRIBED AS FOLLOWS:

BEGINNING AT THE SOUTHEAST CORNER OF SAID LOT 80; THENCE ALONG THE EAST LINE OF SAID LOT 80, NORTH 00°05′30″ EAST, 8.52 FEET; THENCE NORTH 71°34′43″ WEST, 52.71 FEET TO THE WEST LINE OF SAID LOT 80; THENCE ALONG SAID WEST LINE, SOUTH 00°04′35″ WEST, 8.52 FEET TO THE SOUTH LINE OF SAID LOT 80; THENCE ALONG THE SOUTH LINE OF SAID LOT 80, SOUTH 71°34′48″ EAST, 52.71 FEET TO SAID SOUTHEAST CORNER AND THE POINT OF BEGINNING.

PARCEL 57: (APN: 687–205–011)

LOT 81 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA. EXCEPTING THEREFROM, THE EAST 5.00 FEET AND 2.00 INCHES, THEREOF. ALSO EXCEPTING THEREFROM, THAT PORTION CONDEMNED TO THE CITY OF CATHEDRAL CITY, AS DISCLOSED BY DOCUMENT RECORDED MARCH 24, 1999 AS INSTRUMENT NO. 99–121245 AND MAY 17, 1999 AS INSTRUMENT NO. 99–212072, BOTH OF OFFICIAL RECORDS, DESCRIBED AS FOLLOWS:

BEGINNING AT THE SOUTHWEST CORNER OF SAID LOT 81; THENCE ALONG THE WEST LINE OF SAID LOT 81, NORTH 00°05′30″ EAST, 8.52 FEET; THENCE SOUTH 71°34′43″ EAST, 47.24 FEET TO THE WEST LINE OF THE EASTERLY 5.00 FEET 2.00 INCHES OF SAID LOT 81; THENCE ALONG LAST SAID WEST LINE, SOUTH 00°06′25″ WEST, 6.52 FEET TO THE SOUTH LINE OF SAID LOT 81; THENCE ALONG THE SOUTH LINE OF SAID LOT 81, NORTH 71°34′48″ WEST, 47.24 FEET TO SAID SOUTHWEST CORNER AND THE POINT OF BEGINNING.

PARCEL 58: (APN: 687–205–012)

LOT 82 AND THE EAST 5.00 FEET AND 2.00 INCHES OF LOT 81 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24, 25 AND 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, SAID DISTANCE BEING MEASURED ON THE NORTHERLY LINE OF SAID LOT 81.

EXCEPTING THEREFROM, THAT PORTION CONDEMNED TO THE CITY OF CATHEDRAL CITY, AS DISCLOSED BY DOCUMENT RECORDED JULY 12, 1999 AS INSTRUMENT NO. 99–310247 OF OFFICIAL RECORDS, DESCRIBED AS FOLLOWS: BEGINNING AT THE NORTHEAST CORNER OF SAID LOT 82; THENCE ALONG THE NORTH LINE OF SAID LOT 82, NORTH 89°53′57″ WEST, 4.00 FEET TO A LINE THAT IS PARALLEL WITH AND DISTANCE 4.00 FEET WESTERLY, MEASURED AT RIGHT ANGLES, FROM THE EASTERLY LINE OF SAID LOT; THENCE ALONG SAID PARALLEL LINE, SOUTH 00°07′29″ WEST, 137.59 FEET; THENCE SOUTH 63°01′46″ WEST, 6.24 FEET; THENCE NORTH 71°34′43″ WEST, 48.10 FEET TO THE WESTERLY LINE OF THE EASTERLY 5.00 FEET AND 2.00 INCHES OF SAID LOT 81; THENCE ALONG LAST SAID LINE SOUTH 00°07′01″ WEST, 6.41 FEET TO THE SOUTHERLY LINE OF SAID LOT 81; THENCE ALONG THE SOUTHERLY LINE OF SAID LOT 81 SOUTH 71°34′48″ EAST, 1.84 FEET TO AN ANGLE POINT IN THE NORTHERLY LINE OF EAST PALM CANYON DRIVE; THENCE ALONG THE SOUTHERLY LINE OF SAID LOT 81 AND 82 SOUTH 71°36′27″ EAST, 56.31 FEET TO THE SOUTHEAST CORNER OF SAID LOT 82; THENCE ALONG THE EAST LINE OF SAID LOT 82, NORTH 00°07′29″ EAST, 149.98 FEET TO THE POINT OF BEGINNING.

PARCEL 59:

THOSE PORTIONS OF LOT ''C'' (GROVE STREET), LOT ''D'' (GROVE STREET), LOT ''E'' (DAWES STREET), LOT ''F'' (DAWES STREET), LOT ''G'' (ALLEN AVENUE), LOT ''H'' (ALLEY LOT), LOT ''I'' (DATE PALM DRIVE), AND LOT ''X'' (GROVE STREET), AS SHOWN ON THE MAP OF CATHEDRAL CITY, FILED IN BOOK 13, AT PAGES 24 THROUGH 26 OF MAPS, RECORDS OF

RIVERSIDE COUNTY, CALIFORNIA, ALL LOCATED WITHIN THE EAST HALF OF THE EAST HALF OF SECTION 33, TOWNSHIP 4 SOUTH, RANGE 5 EAST, SAN BERNARDINO MERIDIAN, DESCRIBED AS FOLLOWS:

SEGMENT 1:

ALL OF LOT ''C'' (GROVE STREET), AS SHOWN ON SAID MAP OF CATHEDRAL CITY.

SEGMENT 2:

ALL OF LOT ''D'' (GROVE STREET), AS SHOWN ON SAID MAP.

SEGMENT 3:

THE EAST 250 FEET OF LOT ''X'' (GROVE STREET), AS SHOWN ON SAID MAP.

SEGMENT 4:

ALL OF LOT ''E'' (DAWES STREET), AS SHOWN ON SAID MAP.

SEGMENT 5:

ALL OF LOT ''F'' (DAWES STREET), AS SHOWN ON SAID MAP.

SEGMENT 6:

THAT PORTION OF LOT ''G'' (ALLEN AVENUE), AS SHOWN ON SAID MAP, BOUNDED ON THE NORTH BY THE WESTERLY PROLONGATION OF THE NORTH LINE OF LOT ''C'' (GROVE STREET), AND BOUNDED SOUTHWESTERLY BY A LINE PARALLEL WITH AND LOCATED NORTHEASTERLY 67.54 FEET, MEASURED AT RIGHT ANGLES, FROM THE CENTERLINE OF BROADWAY, AS SHOWN ON SAID MAP.

SEGMENT 7:

THAT PORTION OF LOT ''H'' (ALLEY), AS SHOWN ON SAID MAP, BOUNDED ON THE NORTH BY THE EASTERLY PROLONGATION OF THE NORTH LINE OF LOT ''C'' (GROVE STREET) AND BOUNDED ON THE SOUTH BY THE EASTERLY PROLONGATION OF THE SOUTH LINE OF SAID LOT ''F'' (DAWES STREET).

SEGMENT 8:

ALL OF LOT ''I'' (DATE PALM DRIVE), AS SHOWN ON SAID MAP OF CATHEDRAL CITY.

Correction to Quitclaim Deed recorded February 21, 2019 as Instrument No. 2019–0058438 of Official Records.

PARCEL 60: (PARCEL A)

THAT PORTION OF LOT 49 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, DESCRIBED IN DEED TO THE COUNTY OF RIVERSIDE, RECORDED ON JANUARY 15, 1973 AS INSTRUMENT NO. 5715, OF OFFICIAL RECORDS, DESCRIBED AS FOLLOWS:

PARCEL 1: THE NORTHERLY 10.00 FEET OF THE EASTERLY 80.00 FEET OF SAID LOT 49 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 2: A TRIANGULAR SHAPED PARCEL OF LAND LYING WITHIN SAID LOT 49 OF CATHEDRAL CITY, BOUNDED AS FOLLOWS:

BOUNDED ON THE NORTH BY THE SOUTHERLY LINE OF PARCEL 1 ABOVE DESCRIBED; AND BOUNDED ON THE EAST BY THE EASTERLY LINE OF SAID LOT 49; AND BOUNDED ON THE SOUTHWEST BY THE ARC OF A 20.00 FOOT RADIUS CURVE CONCAVE SOUTHWESTERLY AND BEING TANGENT TO EACH OF THE LAST TWO ABOVE DESCRIBED BOUNDARIES.

PARCEL 61: (PARCEL B)

THAT PORTION OF LOT 95 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, DESCRIBED IN DEED TO THE COUNTY OF RIVERSIDE, RECORDED ON MAY 18, 1977, AS INSTRUMENT NO. 89251, IN OFFICIAL RECORDS, DESCRIBED AS FOLLOWS:

PARCEL 1: BEGINNING AT THE NORTHEAST CORNER OF SAID LOT 95; THENCE, ALONG THE NORTH LINE OF SAID LOT 95, NORTH 89°54′00″ WEST, 13.00 FEET; THENCE SOUTH 31°39′54″ EAST, 24.70 FEET TO A POINT IN THE EAST LINE OF SAID LOT 95; THENCE ALONG SAID EAST LINE NORTH 00°05′00″ EAST, 21.00 FEET TO THE POINT OF BEGINNING.

PARCEL 2: BEGINNING AT THE SOUTHEAST CORNER OF SAID LOT 95; THENCE ALONG THE EAST LINE OF SAID LOT 95, NORTH 00°05′00″ EAST, 22, 21 FEET; THENCE SOUTH 48°45′02″ WEST, 24.43 FEET TO A POINT ON THE SOUTHERLY LINE OF SAID LOT 95; THENCE ALONG SAID SOUTHERLY LINE SOUTH 71°35′00″ EAST, 19.33 FEET TO THE POINT OF BEGINNING.

PARCEL 62: (PARCEL C)

THOSE PORTIONS OF LOTS 101, 102 AND 103, AND LOT ''F'' (DAWES STREET) OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, CONVEYED TO THE CITY OF CATHEDRAL CITY, BY DEED RECORDED MAY 12, 1982 AS INSTRUMENT NO. 81733 OF OFFICIAL RECORDS, DESCRIBED AS FOLLOWS:

PARCEL 1: THE NORTH 5.00 FEET OF LOTS 101, 102, AND 103 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGES 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

PARCEL 2: THAT PORTION OF SAID LOT ''F'', 40 FEET WIDE, APPURTENANT TO SAID LOTS 101, 102, AND 103.

PARCEL 63: (PARCEL D)

THAT PORTION OF LOT 82, OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGE 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, DESCRIBED AS ''PARCEL 687–205–004'' IN THAT CERTAIN JUDGMENT AND FINAL ORDER OF CONDEMNATION RECORDED JULY 12, 1999 AS INSTRUMENT NO. 99–310247 OF OFFICIAL RECORDS, LYING NORTHERLY OF A LINE PARALLEL WITH AND LOCATED NORTHEASTERLY 67.54 FEET, MEASURED AT RIGHT ANGLES, FROM THE CENTERLINE OF BROADWAY, AS SHOWN ON SAID MAP.

PARCEL 64: (PARCEL E)

THAT PORTION OF LOT 104, OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE BOOK 13, PAGE 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, ACQUIRED BY THE CITY OF CATHEDRAL CITY BY GRANT DEED RECORDED FEBRUARY 24, 1997 AS INSTRUMENT NO. 97–60589 OF OFFICIAL RECORDS OF RIVERSIDE COUNTY, CALIFORNIA, DESCRIBED AS FOLLOWS:

BEGINNING AT THE NORTHWEST CORNER OF SAID LOT 104; THENCE ALONG THE NORTH LINE OF SAID LOT, SOUTH 89°53′55″ EAST, 30.01 FEET; THENCE SOUTH 00°05′32″ WEST, 11.21 FEET; THENCE NORTH 71°34′43″ WEST, 31.61 FEET TO A POINT ON THE WEST LINE OF SAID LOT 104; THENCE NORTH 00°05′29″ EAST ALONG THE SAID WEST LINE, 1.27 FEET TO THE POINT OF BEGINNING. RESERVING OVER, UNDER, ACROSS, AND THROUGH THE ABOVE DESCRIBED PARCEL A THROUGH PARCEL E AN EASEMENT AND RIGHT OF WAY IN FAVOR OF THE CITY OF CATHEDRAL CITY FOR PUBLIC HIGHWAY AND PUBLIC UTILITY, DRAINAGE, WATERMAIN, SEWER, AND PUBLIC SERVICES PURPOSES.

Correction No. 2 to Quitclaim Deed recorded May 31, 2019 as Instrument No. 2019–0195712 of Official Records.

PARCEL 65: (PARCEL 1—APN: 687–208–023)

LOTS 101 AND 102 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGE 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

TOGETHER WITH THAT PORTION OF A 20.00 FOOT ALLEY, VACATED AND CLOSED TO PUBLIC USE BY RESOLUTION NO. 79–346, OF THE COUNTY OF RIVERSIDE, RECORDED NOVEMBER 21, 1979 AS INSTRUMENT NO. 248832 OF OFFICIAL RECORDS.

EXCEPTING THEREFROM, THAT PORTION CONVEYED TO THE CITY OF CATHEDRAL CITY, IN DEED RECORDED MAY 12, 1982 AS INSTRUMENT NO. 81733 OF OFFICIAL RECORDS.

EXCEPTING THEREFROM, THAT PORTION CONVEYED TO THE CITY OF CATHEDRAL CITY, IN DEEDS RECORDED AUGUST 31, 1982 AS INSTRUMENT NO. 150864 AND JANUARY 25, 1983 AS INSTRUMENT NO. 15185, BOTH OF OFFICIAL RECORDS.

ALSO EXCEPTING THEREFROM, THAT PORTION CONVEYED TO THE CITY OF CATHEDRAL CITY IN DEED RECORDED NOVEMBER 13, 1997 AS INSTRUMENT NO. 97–416611 OF OFFICIAL RECORDS.

PARCEL 66: (PARCEL 2—APN: 687–208–024)

LOT 103 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGE 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPTING THEREFROM, THAT PORTION CONVEYED TO THE CITY OF CATHEDRAL CITY, IN DEEDS AUGUST 31, 1982 AS INSTRUMENT NO. 150864, MAY 12, 1982, AS INSTRUMENT NO. 81733 AND JANUARY 25, 1983 AS INSTRUMENT NO. 15185, ALL OF OFFICIAL RECORDS.

EXCEPTING THEREFROM, THAT PORTION CONVEYED TO THE CITY OF CATHEDRAL CITY IN DEED RECORDED NOVEMBER 13, 1997 AS INSTRUMENT NO. 416611 OF OFFICIAL RECORDS.

PARCEL 67: (PARCEL 3—APN: 687–203–025)

LOT 104 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGE 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPTING THEREFROM, THE FOLLOWING DESCRIBED PARCEL OF LAND: BEGINNING AT THE SOUTHWEST CORNER OF SAID LOT 104; THENCE ALONG THE WEST LINE OF SAID LOT NORTH 00°05′29″ EAST, 29.76 FEET TO THE NORTHWEST CORNER THEREOF; THENCE ALONG THE NORTH LINE OF SAID LOT, SOUTH 89°53′55″ EAST, 30.01 FEET; THENCE SOUTH 00°05′32″ WEST, 11.21 FEET; THENCE SOUTH 71°34′43″ EAST, 52.68 FEET TO THE WEST LINE OF THE EAST 50.00 FEET OF SAID LOT; THENCE ALONG LAST SAID WEST LINE SOUTH 00°05′37″ WEST, 28.51 FEET TO THE SOUTHERLY LINE OF SAID LOT; THENCE ALONG SAID SOUTHERLY LINE, NORTH 71°34′04″ WEST, 84.30 FEET TO THE SOUTHWEST CORNER OF SAID LOT 104 AND THE POINT OF BEGINNING. ALSO EXCEPTING THEREFROM, THE EASTERLY 50.00 FEET OF SAID LOT 104.

PARCEL 68: (PARCEL 4—APN: 687–208–026)

THE EAST 50.00 FEET OF LOT 104 OF CATHEDRAL CITY, AS SHOWN BY MAP ON FILE IN BOOK 13, PAGE 24 THROUGH 26 OF MAPS, RECORDS OF RIVERSIDE COUNTY, CALIFORNIA.

EXCEPTING THEREFROM, THE FOLLOWING DESCRIBED PARCEL OF LAND: BEGINNING AT THE SOUTHEAST CORNER OF SAID LOT 104; THENCE ALONG THE EAST LINE OF SAID LOT, NORTH 00°05′42″ EAST, 27.78 FEET TO A NON–TANGENT CURVE CONCAVE SOUTHWESTERLY AND HAVING A RADIUS OF 235.84 FEET, A RADIAL LINE OF SAID CURVE THROUGH SAID POINT BEARS NORTH 22°26′25″ EAST; THENCE NORTHWESTERLY ALONG SAID CURVE, THROUGH A CENTRAL ANGLE OF 03°14′22″, AN ARC DISTANCE OF 13.33 FEET TO THE BEGINNING OF A COMPOUND CURVE CONCAVE SOUTHWESTERLY AND HAVING A RADIUS OF 1,494.89 FEET; THENCE NORTHWESTERLY ALONG SAID CURVE, THROUGH A CENTRAL ANGLE OF 00°46′46″, AN ARC DISTANCE OF 20.33 FEET; THENCE NORTH 71°34′43″ WEST, 19.26 FEET TO THE WEST LINE OF THE EASTERLY 50.00 FEET OF SAID LOT 104; THENCE ALONG LAST SAID WEST LINE SOUTH 00°05′37″ WEST, 28.51 FEET TO THE SOUTHERLY LINE OF SAID LOT; THENCE ALONG SAID SOUTHERLY LINE, SOUTH 71°34′04″ EAST, 52.69 FEET TO THE SOUTHEAST CORNER OF SAID LOT 104 AND THE POINT OF BEGINNING.

Authority: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 Departmental Manual 8.1, and is published to comply with the requirements of 25 CFR 151.12 (c)(2)(ii) that notice of the decision to acquire land in trust be promptly provided in the **Federal Register**.

Dated: November 1, 2019.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2019–24361 Filed 11–7–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORW00000.L10200000.DF0000. 19XL1109AF.LXSSH1070000.HAG 19–0046]

Notice of the John Day-Snake Resource Advisory Council Planning Subcommittee Meeting Schedule

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Planning Subcommittee public meeting schedule.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) the John Day-Snake Resource Advisory Council (RAC) Planning Subcommittee will meet as indicated below.

DATES: The RAC Planning Subcommittee is announcing the availability of scheduled conference calls. The conference call line will be available for the John Day-Snake RAC subcommittee members and designated Federal liaisons on Thursday, December 19, 2019, from 6 p.m. to 8 p.m. and January 22, 2020, from 6 p.m. to 8 p.m.

ADDRESSES: The Subcommittee teleconference number is toll-free and will be published in the agenda on the RAC web page at least 10 days in advance of the call on the RAC web page at: *https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/john-day-rac.*

FOR FURTHER INFORMATION CONTACT: Lisa Clark; Public Affairs Officer; 3050 NE 3rd Street; Prineville, OR 97754; 541–416–6864; *lmclark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The RAC provides recommendations to the Secretary of the Interior on behalf of the BLM and the U.S. Forest Service that identify beneficial ideas and solutions to help shape decisions concerning the planning and management of central and eastern Oregon public lands resources. RACs serve as sounding boards for initiatives, regulatory proposals, and policy changes. Each RAC consists of 10 to 15 citizens that represent diverse interests shared with their community members. RACs play a key role in allowing the BLM to continue to be a good neighbor in the communities we serve.

The meeting scheduled for November 14, 2019, will include a discussion regarding on-going planning in the BLM's Prineville and the Thirtymile Management Plan. The metting scheduled for December 19, 2019, will discuss the Prineville District BLM Lower Deschutes Fee Proposal and public outreach.

The Planning Subcommittee was established to gather information, conduct research, and analyze relevant issues and facts on selected topics for consideration by the RAC. The Subcommittee's primary goal is to provide information to the RAC that allows them to better respond to time-sensitive issues, such as providing responses to an environmental document within the public comment period. No decisions are made at the subcommittee level.

The Designated Federal Officer will attend the call, take minutes, and publish these minutes on the RAC web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/john-day-rac.*

All calls/meetings are open to the public in their entirety. The public may send written comments to the Subcommittee in response to material presented on the call to be forwarded to the RAC for consideration. Comments can be mailed to: BLM Prineville District; Attn. Lisa Clark; 3050 NE 3rd Street; Prineville, OR 97754.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 1784.4–2.

Dennis C. Teitzel,

Prineville District Manager.

[FR Doc. 2019–24449 Filed 11–7–19; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19XL5017AR.LLUT921000.L54200000.BX0000.LVDIJ19J0010; UTU–94260]

Notice of Application for Recordable Disclaimer of Interest in Public Highway Rights-of-Way; Manganese Road in Washington County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: On May 9, 2019, the State of Utah and Washington County (Applicants) filed an application with the Bureau of Land Management (BLM) for a Recordable Disclaimer of Interest (RDI) from the United States in a public highway right-of-way identified by BLM Serial Number UTU–94260 for Manganese Road in Washington County, Utah. An RDI, if issued, would disclaim the United States' interest in this public highway right-of-way. This Notice is to notify the public of the pending application and the Applicants' grounds supporting it. Specific details of the application are provided in the **SUPPLEMENTARY INFORMATION** section.

DATES: Submit written comments on this application on or before December 9, 2019. Public comments may be mailed or hand delivered to the BLM office address below. Comments on the Manganese Road should reference BLM Serial Number UTU–94260. The BLM will not consider comments received via telephone calls or faxes.

ADDRESSES: You may submit comments via mail or email on the State and Washington County's application for an RDI. Email comments may be submitted to *blm_ut_rdi@blm.gov.* Written comments may be provided to Melinda Moffitt, Project Manager (R.S. 2477), BLM Utah State Office (UT–921), 440 West 200 South, Suite 500, Salt Lake City, Utah 84101–1345.

FOR FURTHER INFORMATION CONTACT: Melinda Moffitt, Project Manager (R.S. 2477), BLM Utah State Office at the above address or phone (801) 539–4045 and email to *blm_ut_rdi@blm.gov.* Persons who use a telecommunication device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact the above individual. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Section 315 of the Federal Land Policy and Management Act (FLPMA) of 1976, as amended (43 U.S.C. 1745), and the regulations at 43 CFR 1864 authorize the BLM to issue an RDI where: (1) The disclaimer will help remove a cloud on title, and (2) a record interest of the United States in lands has terminated by operation of law or is otherwise invalid.

In their application, the Applicants identify that the BLM's continued management and regulation of the Manganese Road, *i.e.,* the claimed Revised Statute (R.S.) 2477 (43 U.S.C. 932, repealed October 21, 1976) right-of-way that is the subject of the application, and the Applicants' Quiet Title Act lawsuit that seeks to quiet title in the road represent a cloud on the Applicants' title. Further, the Applicants assert that they hold a joint and undivided property interest in the public highway right-of-way for the Manganese Road as granted pursuant to the authority provided by R.S. 2477 over public lands administered by the BLM.

The Manganese Road is approximately 10.18 miles in length, located in western Washington County, and it extends from the Gunlock Road west to the Motoqua Road. It crosses approximately 9.88 miles of public lands administered by the BLM in townships 40 south, ranges 17 and 18 west, Salt Lake Meridian, Utah. The RDI application pertains only to those road segments across public lands administered by the BLM. One road segment is approximately 0.3 miles long across private property and is not a part of the application. This private property segment is the eastern 0.3 mile segment of the Manganese Road that connects to the Gunlock Road and crosses sections 28 and 29 of township 40 south, range 17 west, Salt Lake Meridian, Utah.

Application information submitted by the Applicants indicates that initial use of Manganese Road began no later than the 1940s. The road was and currently is used for grazing, ranching, hunting, wood gathering, prospecting, recreation, and general public access in the local area. The surface of the road is gravel and native soil and is graded throughout its length.

The Applicants submitted the following information with the application:

1. Narrative description of the location, characteristics and attributes of Manganese Road. The travel surface width ranges from 21 to 68 feet.

2. Centerline description of the road based on Global Positioning System (GPS) data.

3. Detailed descriptions of the right-of-way passing through public lands including beginning and end points, surface type, and disturbed width.

4. Maps showing the location of the public highway right-of-way.

5. Aerial photography dated 1976.

6. Depositions by seven persons attesting to the location of the road; its establishment as a public highway prior to October 21, 1976; familiarity with the character and attributes of the road including type of travel surface, disturbed width, associated improvements and ancillary features such as culverts, cattle-guards, etc.; current public usage of the road; the historic and current purposes for which the road is used; and evidence of periodic maintenance.

7. Recent photographs and 360 degree video depictions of the road at various points along its alignment.

The Applicants did not identify any known adverse claimants of the public highway right-of-way.

If approved, the RDI document would disclaim the United States' interest in the public highway right-of-way as of the date of the disclaimer document. The BLM's RDI document would disclaim the United States' interest in, or ownership of, specified interests in lands, but the disclaimer would not grant, convey, transfer, remise, quitclaim, release or renounce any title or interest in the lands, nor would it release any tax, judgment, or lien, or any other mortgage, deed or trust, or other security interest in lands that are held by or for the benefit of the United State or any instrumentality of the United States. This Notice is to inform the public of the pending application and the Applicants' supporting evidence, as well as to provide the opportunity to comment or provide additional information to the BLM.

The BLM will not make a final determination on the Applicants' application before February 6, 2020. Interested parties and the public will have 30 days to provide comment and are encouraged to access the BLM RDI public web page at *https://www.blm.gov/programs/lands-and-realty/utah/rdi* to review a copy of the application and supporting evidence. Additionally, copies of the application materials are available for public review at the BLM Utah State Office (see **ADDRESSES** above), during regular business hours, 7:45 a.m. to 4:30 p.m. local time, Monday through Friday, except holidays.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information may be made publicly available at any time. While you can ask the BLM in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 1864.

Edward Roberson,

State Director.

[FR Doc. 2019–24448 Filed 11–7–19; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19XL.LLIDI00000.L71220000.EO0000. LVTFDX508300.241A.4500137846]

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Availability of the Final Environmental Impact Statement for the Proposed Dairy Syncline Mine and Reclamation Plan, Caribou County, Idaho

AGENCY: Bureau of Land Management, Interior; United States Forest Service, Agriculture.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, the Bureau of Land Management (BLM), Idaho Falls District, and the U.S. Department of Agriculture, Forest Service (USFS) Caribou-Targhee National Forest (CTNF), have prepared a Final Environmental Impact Statement (EIS) for the proposed Dairy Syncline Mine Project (Project) and by this notice are announcing its availability. This notice also announces the availability of the associated Proposed Resource Management Plan (RMP) Amendment for the 2012 BLM Pocatello Resource Management Plan, in accordance with the Federal Land Policy and Management Act of 1976, as amended.

DATES: BLM planning regulations state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed RMP Amendment. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency publishes its Notice of Availability (NOA) in the **Federal Register**. A 60-day objection period for the Draft USFS Record of Decision (ROD) will start when the USFS publishes a legal notice in the newspaper of record.

ADDRESSES: Copies of the Dairy Syncline Mine and Reclamation Plan Final EIS and Proposed RMP Amendment are available for public inspection at the BLM Pocatello Field Office at 4350 Cliffs Drive, Pocatello, ID 83204. Interested persons may also review the Final EIS on the internet at the following locations:

- *BLM Land Use Planning and NEPA Register: https://go.usa.gov/xUjcA.*
- Caribou-Targhee National Forest Current and Recent Projects *http://www.fs.usda.gov/projects/ctnf/landmanagement/projects.*

All protests must be in writing and filed with the BLM Director, either as a hard copy or electronically via the BLM's ePlanning project website listed previously. To submit a protest electronically, go to the ePlanning project website and follow the protest instructions highlighted at the top of the home page. If submitting a protest in hard copy, it must be mailed to one of the following addresses:

Regular Mail: BLM Director (210), Attention: Protest Coordinator, P.O. Box 71383, Washington, DC 20024–1383

Overnight Delivery: BLM Director (210), Attention: Protest Coordinator, 20 M Street SE, Room 2134LM, Washington, DC 20003

FOR FURTHER INFORMATION CONTACT: Bill Stout, BLM Pocatello Field Office, 4350 Cliffs Drive, Pocatello, ID 83204; phone (208) 478–6367; email: *jwstout@blm.gov;* fax (208) 478–6376. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Stout. The FRS is available 24 hours a day, 7 days a week, to leave a message or question for Mr. Stout. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The J.R. Simplot Company (Simplot) submitted a Mine and Reclamation Plan (MRP) application for agency review to extract phosphate rock from the Dairy Syncline leases (IDI–28115 and IDI–0258) located approximately 14 miles east of Soda Springs in Caribou County, Idaho.

The BLM, as the Federal mineral lease administrator, is the lead agency, and the USFS is the co-lead agency for preparation of the EIS. The proposed project would disturb about 2,770 acres as described in the Final EIS. In order to accommodate the proposed tailings pond, the BLM proposes a land sale and the USFS is considering a land exchange. The BLM land sale would require an amendment to the current Pocatello RMP and the land exchange would require a Forest Plan Amendment. The proposed decision to amend the 2012 Pocatello RMP clarifies that the lands proposed for sale meet the FLPMA 203(a) sale criteria and is the only decision subject to protest.

The NOA for the Draft EIS published on November 23, 2018, initiating a 90-day public comment period. Agencies, organizations, and interested parties provided comments on the Draft EIS/Draft RMP Amendment via mail, email, and public meetings. Comments on the Draft EIS/Draft RMP Amendment received from the public and internal BLM review were considered and incorporated, as appropriate, into the Final EIS and proposed plan amendment. Public comments resulted in the addition of clarifying text, but did not significantly change the proposed land use plan decisions.

The Final EIS fully addresses issues identified during scoping and during public review of the Draft EIS, and evaluates alternatives to the Proposed Action, including a No Action Alternative. The agency Preferred Alternative is the Proposed Action modified by Alternative 3 (reduces acreage of BLM land sale), Alternative 5 (reduce acreage of USFS land exchange), and Alternative 6 (reduces impacts to groundwater). The modifications made to the Proposed Action, making up the Preferred Alternative, result in a net gain of Federal land acreage and the fewest impacts to surface and groundwater of all the action alternatives.

Instructions for filing a protest with the Director of the BLM regarding the Proposed RMP Amendment may be found online at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above or submitted electronically through the BLM ePlanning project website as described above. Protests submitted electronically by any means other than the ePlanning project website protest section will be invalid unless a protest is also submitted in hard copy. Protests submitted by fax will also be invalid unless also submitted either through the ePlanning project website or in hard copy.

The BLM and USFS will make separate but coordinated decisions

related to the proposed Project. The BLM decisions are related to: (1) Approval of the MRP and/or alternatives; (2) enlargement (modification) of the existing leases; (3) approval of the Resource Management Plan amendment for the land sale; (4) approval of the land sale as proposed or modified; and (5) acceptance of the 440-acre parcel donated by Simplot.

The USFS will provide a recommendation to BLM regarding surface management and the selected alternative on leased National Forest System lands. The USFS will make decisions related to: (1) Approval of the land exchange; (2) acceptance of the donation parcel; (3) Roadless Area boundary changes; (4) Special Use Authorizations for off-lease activities; and (5) amendments to the 2003 Revised Forest Plan for the Caribou National Forest to add management prescriptions and designate utility corridors.

The USFS decisions are subject to the objection process pursuant to 36 CFR 218 and 219. The USFS will provide instructions for filing objections to the Draft USFS ROD in the legal notice published in the newspaper of record. The USFS will only accept objections from those who have previously submitted specific written comments regarding the proposed project during scoping or other designated opportunities for public comment in accordance with 36 CFR 218.5(a) and 219.53(a). Objection issues must be based on previously submitted, timely, and specific written comments regarding the proposed project unless based on new information arising after designated opportunities. The BLM will release a ROD concurrent with release of the USFS Final ROD.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 36 CFR 218 and 219; 40 CFR 1506.6 and 1506.10; 43 CFR 1610.2 and 3590.

John F. Ruhs,

State Director, Bureau of Land Management, Idaho State Office.

Mel Bolling,

Forest Supervisor, Caribou-Targhee National Forest.

[FR Doc. 2019–24218 Filed 11–7–19; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029120; PCU00RP14.R50000–PPWOCRADN0]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of the Interior, Bureau of Indian Affairs has corrected an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on February 8, 2019. This notice corrects the number of associated funerary objects.

ADDRESSES: Anna Pardo, Museum Program Manager/NAGPRA Coordinator, U.S. Department of the Interior, Bureau of Indian Affairs, 12220 Sunrise Valley Drive, Room 6084, Reston, VA 20191, telephone (703) 390–6343, email *Anna.Pardo@bia.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of associated funerary objects under the control of the U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC. The human remains and associated funerary objects were removed from sites on and around Black Mesa and Klethla Valley in Coconino and Navajo Counties, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the number of associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (84 FR 2920–2921, February 8, 2019). Additional associated funerary objects were located during preparations for repatriation.

Correction

In the **Federal Register** (84 FR 2921, February 8, 2019), column 2, paragraph 2, sentence 3 is corrected by substituting the following sentence:

The 10,951 associated funerary objects include ceramic vessels, beads, pollen and soil samples, sherds, lithics, plant and wood materials, groundstone, shells, and faunal remains.

In the **Federal Register** (84 FR 2921, February 8, 2019), column 2, paragraph 3, sentence 3 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(3)(A), the 10,951 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

For questions related to this notice, contact Anna Pardo, Museum Program Manager/NAGPRA Coordinator, U.S. Department of the Interior, Bureau of Indian Affairs, 12220 Sunrise Valley Drive, Room 6084, Reston, VA 20191, telephone (703) 390–6343, email *Anna.Pardo@bia.gov.*

The U.S. Department of the Interior, Bureau of Indian Affairs is responsible for notifying the Hopi Tribe of Arizona; Navajo Nation, Arizona, New Mexico & Utah; and the Zuni Tribe of the Zuni Reservation, New Mexico, that this notice has been published.

Dated: October 15, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24399 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029073; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: South Dakota State Historical Society, Archaeological Research Center, Rapid City, SD

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The South Dakota State Historical Society, Archaeological Research Center has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated

funerary objects should submit a written request to the South Dakota State Historical Society, Archaeological Research Center. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the South Dakota State Historical Society, Archaeological Research Center at the address in this notice by December 9, 2019.

ADDRESSES: Katherine Lamie, South Dakota State Historical Society-Archaeological Research Center, 217 Kansas City Street, Rapid City, SD 57701, telephone (605) 394–1804, email *katie.lamie@state.sd.us.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the South Dakota State Historical Society, Archaeological Research Center, Rapid City, SD. The human remains and associated funerary objects were removed from Marshall County, SD.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the South Dakota State Historical Society, Archaeological Research Center professional staff in consultation with representatives of the Oglala Sioux Tribe (previously listed as the Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota); Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Santee Sioux Nation, Nebraska; Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota; Spirit Lake Tribe, North Dakota; Standing Rock Sioux Tribe of North & South Dakota; and the Upper Sioux Community, Minnesota.

The following Indian Tribes were invited to consult, but deferred to the consulting Tribes by submitting letters of support: Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma); Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Otoe-Missouria Tribe of Indians, Oklahoma; Pawnee Nation of Oklahoma; Prairie Island Indian Community in the State of Minnesota; and the Shakopee Mdewakanton Sioux Community of Minnesota.

The following Indian Tribes were invited to consult, but did not participate: Arapaho Tribe of the Wind River Reservation, Wyoming; Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana; Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Cheyenne River Sioux Tribe of the Cheyenne River Indian Reservation, South Dakota; Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana (previously listed as the Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana); Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Crow Tribe of Montana; Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (previously listed as the Shoshone Tribe of the Wind River Reservation, Wyoming); Flandreau Santee Sioux Tribe of South Dakota; Forest County Potawatomi Community, Wisconsin; Fort Belknap Indian Community of the Fort Belknap Reservation of Montana; Ho-Chunk Nation of Wisconsin; Iowa Tribe of Kansas and Nebraska; Iowa Tribe of Oklahoma; Kiowa Indian Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota; Lower Sioux Indian Community in the State of Minnesota; Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Omaha Tribe of Nebraska; Ponca Tribe of Indians of Oklahoma; Ponca Tribe of Nebraska; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; Turtle Mountain Band of Chippewa Indians of North Dakota; Winnebago Tribe of Nebraska; and the Yankton Sioux Tribe of South Dakota.

Hereafter, all tribes listed in this section are referred to as ''The Consulted and Notified Tribes.''

History and Description of the Remains

In the 1970s, human remains representing, at minimum, one individual were removed from site 39ML11 in Marshall County, SD, by the private landowner. The landowner had discovered cranial and post cranial human remains while picking rocks in a former gravel pit. In 1998, the landowner showed the Marshall County Sheriff where the human remains were found, and turned the human remains over to law enforcement. The Marshall County Sheriff's Office then transferred the human remains to the Archaeological Research Center (accession 99–0064). The human remains belong to an adult male, 40–50 years old. No known individuals were identified. No associated funerary objects are present.

Site 39ML11 is recorded as a historic military installation associated with Fort Sisseton, which is located farther to the west. However, a physical anthropological assessment determined that the robust morphological features on the skeletal remains are consistent with populations that date to the Northeast Plains Woodland Period (400 B.C. to A.D. 1250).

At an unknown date, human remains representing, at minimum, six individuals were removed from Marshall County, SD. At an unknown date, the human remains were given to the Prayer Rock Museum, which has no documentation on the human remains. In May 2005, a human cranium, representing one of the six individuals, was delivered to the Marshall County Sheriff's Office by a museum board member who discovered the human remains in a box at the museum. In June 2005, the Marshall County Sheriff's Office transferred the cranium to the Archaeological Research Center (accession 05–0289). In December 2005, human remains representing the other five individuals were delivered to the Marshall County Sheriff's Office after the new property owner discovered them in a shed that was attached to the former Prayer Rock Museum building. In December 2005, the Marshall County Sheriff's Office transferred these additional human remains to the Archaeological Research Center (added

to accession 05–0289). The human remains belong to one male adolescent, one female adolescent, two female young adults, one male young adult, and one male adult. All of the human remains are characterized by affixed soil and degrees of soil staining. Some elements show differential bleaching from exposure to sunlight, which suggests that they may have been originally recovered from a disturbed or eroded burial context. No known individuals were identified. No associated funerary objects are present.

Based on their physical condition, the human remains were most likely interred below the ground surface over 100 years ago. Whether the six individuals were interred within the same burial feature is unclear. The human remains are most likely Native American based on their morphological features and tooth wear pattern.

In 2010, human remains representing, at minimum, three individuals were removed from site 39ML18 in Marshall County, SD, by archeologists from the Archaeological Research Center during the investigation of a burial disturbance. All skeletal elements and associated funerary objects were recovered out of context, in previously disturbed fill that had been imported by the landowner from a former gravel pit as part of a home remodeling project. According to the landowner, human skeletal remains were rumored to have been discovered during gravel pit operations at the same location by county personnel in the 1940s and 1950s. The human remains and associated funerary objects recovered from the site were brought to the Archaeological Research Center for documentation at the completion of the field investigation (accession 10–0137). A physical anthropological assessment determined that the fragmentary skeletal elements are consistent with Native American archeological remains, and represent two adult males and one sub-adult of indeterminate sex, 2.5 to 3.5 years old. No known individuals were identified. The four associated funerary objects are one soil sample, one chert shatter, one possible stone bead, and one stone sample.

Site 39ML18 was initially documented in the late 1800s as one of several local burial mound sites overlooking Kettle Lake near Fort Sisseton. Based on morphological features and the probable original burial context, the human remains may date to the Northeast Plains Woodland Period (400 B.C. to A.D. 1250).

Determinations Made by the South Dakota State Historical Society, Archaeological Research Center

Officials of the South Dakota State Historical Society, Archaeological Research Center have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on a physical anthropological assessment and an evaluation of the manner and location of burial.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of ten individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the four objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to the Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Katherine Lamie, South Dakota State Historical Society-Archaeological Research Center, 217 Kansas City Street, Rapid City, SD 57701, telephone (605) 394–1804, email *katie.lamie@state.sd.us,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota may proceed.

The South Dakota State Historical Society, Archaeological Research Center is responsible for notifying The Consulted and Notified Tribes that this notice has been published.

Dated: October 4, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24395 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029124; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Arkansas Archeological Survey, Fayetteville, AR; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Arkansas Archeological Survey has corrected an inventory of human remains published in a Notice of Inventory Completion in the **Federal Register** on February 24, 2017. This notice corrects the minimum number of individuals. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Arkansas Archeological Survey. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Arkansas Archeological Survey at the address in this notice by December 9, 2019.

ADDRESSES: Dr. George Sabo, Arkansas Archeological Survey, 2475 N Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556, email *gsabo@uark.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C.

3003, of the correction of an inventory of human remains under the control of the Arkansas Archeological Survey, Fayetteville, AR. The human remains were removed from Arkansas County, AR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the minimum number of individuals published in a Notice of Inventory Completion in the **Federal Register** (82 FR 11608–11617, February 24, 2017). Private individuals removed the human remains from Arkansas County in the 1930s and 1940s. These collections were acquired by the Joint Educational Consortium of Henderson State University and Ouachita Baptist University in 1977 and were transferred to the Arkansas Archeological Survey in 2017 to undergo the NAGPRA process. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (82 FR 11608, February 24, 2017), column 3, paragraph 1, sentence 1 is corrected by substituting the following sentence:

In the 1930s to 1940s and in 1996, human remains representing a minimum of two individuals were recovered from the Wallace site (3AR25) in Arkansas County, Arkansas.

In the **Federal Register** (82 FR 11608, February 24, 2017), column 3, paragraph 1, sentence 4 is corrected by substituting the following sentence:

Diagnostic artifacts found at the Wallace site (3AR25) indicate that these human remains were probably buried during the Mississippi Period (A.D. 950–1541) or the Protohistoric Period (A.D. 1500–1700).

In the **Federal Register** (82 FR 11617, February 24, 2017), column 1, paragraph 1, sentence 1 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 277 individuals of Native American Ancestry.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. George Sabo, Arkansas Archeological Survey, 2475 N Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556, email *gsabo@uark.edu,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Quapaw Tribe of Indians may proceed.

The Arkansas Archeological Survey is responsible for notifying The Quapaw Tribe of Indians that this notice has been published.

Dated: October 15, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24397 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029119; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Robert S. Peabody Institute of Archaeology, Andover, MA; Correction; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Robert S. Peabody Institute of Archaeology (formerly the Robert S. Peabody Museum of Archaeology) has corrected an inventory of associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on September 22, 2017 and amended in a Notice of Inventory Completion Correction published in the **Federal Register** on January 30, 2018. This notice further corrects the number of associated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request to the Robert S. Peabody Institute of Archaeology. If no additional requestors come forward, transfer of control of the associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to the Robert S. Peabody Institute of Archaeology at the address in this notice by December 9, 2019.

ADDRESSES: Ryan Wheeler, Robert S. Peabody Institute of Archaeology, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of associated funerary objects under the control of the Robert S. Peabody Institute of Archaeology, Andover, MA. The associated funerary objects were removed from Mansion Inn site, Wayland, Middlesex County, MA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice further corrects the number and types of associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (82 FR 44460–44461, September 22, 2017) and amended in a Notice of Inventory Completion Correction in the **Federal Register** (83 FR 4266–4267, January 30, 2018). In June 2019, the Wayland Archaeological Research Group (WARG) transferred associated funerary objects to the Robert S. Peabody Institute of Archaeology to aid in the repatriation of objects from the Mansion Inn site (19–MD–210). These associated funerary objects were originally collected by Duncan Ritchie, Herbert Ross, and Curtis Chapin and some had been curated at the now defunct Elbanobscot Foundation Inc., Sudbury, MA. The updated counts and types of associated funerary objects reflect the inclusion of the WARG transfer. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (82 FR 44461, September 22, 2017), column 2, paragraph 1, sentence 1 is corrected by substituting the following sentence:

In June 1959, 274 associated funerary objects were removed from the Mansion Inn site (19–MD–210) in Middlesex County, MA.

In the **Federal Register** (82 FR 44461, September 22, 2017), column 2, paragraph 1, sentence 6 is corrected by substituting the following sentence:

Human remains and funerary objects removed by Johnson, Curtis Chapin, Duncan

Ritchie, Herbert Ross, and others were ultimately preserved in the Robert S. Peabody Institute of Archaeology, the Massachusetts Archaeological Society/Robbins Museum, the Elbanobscot Foundation Inc., and the Wayland Archaeological Research Group.

In the **Federal Register** (83 FR 4266, January 30, 2018), column 3, full paragraph 3, under the heading ''Correction'', is corrected by substituting the following sentence:

The 274 associated funerary objects are three adze fragments; one axe fragment; 121 bifaces and biface fragments; 18 flakes/debitage; 11 lots, flakes/debitage; one lot, calcined bone fragments; two charcoal samples; one charred nut fragment; one hammerstone; 22 worked and unworked pebbles and pebble fragments; 22 biface preform fragments; one shark tooth; one ceramic sherd; one lot, red ochre and animal bone fragments; 18 groundstone fragments; 10 fragments, fire cracked rock; one thumbnail scraper; and 39 unworked stone fragments.

In the **Federal Register** (83 FR 4266, January 30, 2018), column 3, full paragraph 4, under the heading ''Correction'', is corrected by replacing the number ''178'' with ''274''.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to Ryan Wheeler, Robert S. Peabody Institute of Archaeology, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the associated funerary objects to the Wampanoag Repatriation Confederation, representing the Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.) and the Wampanoag Tribe of Gay Head (Aquinnah), and, if joined to one or more of the above Tribes, the Assonet Band of the Wampanoag Nation and Nipmuc Nation, which are non-federally recognized Indian groups, may proceed.

The Robert S. Peabody Institute of Archaeology is responsible for notifying the Wampanoag Repatriation Confederation, representing the Mashpee Wampanoag Tribe (previously listed as the Mashpee Wampanoag Indian Tribal Council, Inc.) and the Wampanoag Tribe of Gay Head (Aquinnah), and, if joined to one or more of the above Tribes, the Assonet Band of the Wampanoag Nation and Nipmuc Nation, which are non-federally recognized Indian groups, that this notice has been published.

Dated: October 15, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24400 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029069: PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of Tennessee, Department of Anthropology, Knoxville, TN, and U.S. Army Corps of Engineers, Omaha District, Omaha, NE

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Tennessee, Department of Anthropology (UTK) and the U.S. Army Corps of Engineers, Omaha District (Omaha District) have completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and have determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to UTK and Omaha District. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to UTK and Omaha District at the address in this notice by December 9, 2019.

ADDRESSES: Dr. Robert Hinde, University of Tennessee, Office of the Provost, 527 Andy Holt Tower, Knoxville, TN 37996–0152, telephone (865) 974–2445, email *rhinde@utk.edu* and *vpaa@utk.edu*. Ms. Sandra Barnum, U.S. Army Engineer District, Omaha, ATTN: CENWO–PM–AB, 1616 Capital Avenue, Omaha, NE 68102, telephone (402) 995–2674, email *sandra.v.barnum@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the University of Tennessee, Department of Anthropology, Knoxville, TN, and the U.S. Army Corps of Engineers, Omaha District, Omaha, NE. The human remains and associated funerary objects were removed from Campbell, Corson, and Walworth Counties, SD.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by UTK professional staff in consultation with representatives of the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

History and Description of the Remains

During the summers of 1965, 1966, 1968, 1969, 1970, and 1973, human remains representing, at minimum, 125 individuals were removed from 39CA4, the Anton Rygh site, in Campbell County, SD, under the direction of William Bass. Post-excavation, Bass transferred the human remains to the University of Kansas. In 1971, Bass transferred the human remains to UTK. The human skeletal remains include 39 infants and 18 children, all of indeterminate sex, nine adolescents, and 59 adults. Of the adolescent individuals, five are probably male and four are of indeterminate sex. Of the adults, 30 are probably male, 22 are probably female, and seven are of indeterminate sex. No known individuals were identified. The 28 associated funerary objects include 14 lots of botanicals, two lots of ceramics, seven lots of fauna, three lots of lithics, and two lots of minerals.

Around November 1980, human remains representing, at minimum, one individual were removed from 39CA4, the Anton Rygh site, in Campbell County, SD, by an individual named

Lewellyn. At an unknown date, likely prior to the 1990s, these human remains were transferred to William Bass at UTK. The human skeletal remains belong to an adolescent, 16–20 years old and possibly female. No known individuals were identified. No associated funerary objects are present.

At an unknown date, likely around the 1960s, human remains representing, at minimum, seven individuals were removed from 39CA4, the Anton Rygh site, in Campbell County, SD, by Guy Gage and John Ospeth. At an unknown date, likely prior to the 1990s, these human remains were transferred to William Bass at UTK. The human skeletal remains belong to seven adults. Of the adults, two are probably male, four are probably female, and one is of indeterminate sex. No known individuals were identified. No associated funerary objects are present.

Site 39CA4 is a large, multi-component earth lodge village, part of the Plains Village Tradition. It is a fortified village site covering around 11–12 acres. At least two occupations are suggested by archeological evidence. The first occupation dates to the Extended Middle Missouri period (A.D. 1000–1500), while the second occupation dates to the Extended Coalescent (A.D. 1500–1675) and Post Contact Coalescent (A.D. 1675–1780) periods. Anthropological, archeological and biological evidence support a finding that during the Extended Middle Missouri period, this area was ancestral Mandan territory, while during the Extended Coalescent and Post Contact Coalescent periods, this area was ancestral Arikara territory. Today, the Mandan and Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

During the summers of 1965, 1966, 1969 and 1970, human remains representing, at minimum, 341 individuals were removed from 39CO9, the Leavenworth site, in Corson County, SD, under the direction of William Bass. After the excavations, Bass transferred the human remains to the University of Kansas. In 1971, Bass moved from Kansas to UTK and took the human remains with him. The human skeletal remains include a minimum of 133 infants and 51 children, all of indeterminate sex, 28 adolescents, and 129 adults. Of the adolescents, two are probably male, 11 are probably female, and 15 are of indeterminate sex. Of the adults, 54 are probably male, 53 are probably female, and 22 are of indeterminate sex. No known individuals were identified. The 1,179 associated funerary objects include 43 lots of botanicals (wood and seeds); 30 lots of ceramics; 13 lots of cloth; 258 lots of fauna (animal bones, teeth, shell and hide); 464 lots of glass that include beads; 61 lots of lithics; 229 lots of metal items; 39 lots of minerals; 41 lots of rocks; and one lot of burial sediment.

The Leavenworth site dates to circa A.D. 1800 to 1832. It comprises a village and cemetery. The Leavenworth site is discussed in a number of historical documents, including those of French fur trader Pierre-Antoine Tabeau, who lived with the Arikara at the Leavenworth site, as well as in the Journals of Lewis and Clark, who visited the site in 1804. The site was attacked by Colonel Leavenworth in 1823. George Catlin passed the still-inhabited site on a steamboat in 1832. In 1834, Maximilian, Prince of Wied, visited the Leavenworth site. Finding it abandoned, he collected some human remains. Excavation and removal of human remains and materials at the site continued during the twentieth century under the direction of various individuals, including W.H. Over, M.W. Stirling, W.D. Strong, J.B. Caldwell and then William Bass. In addition to the historical documents stating that the Arikara inhabited the Leavenworth site, archeological research on the material culture from the site places it within the Post-Contact Coalescent tradition, which is believed to be affiliated with the Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

In July of 1968, human remains representing, at minimum, one individual were removed by Douglas Ubelaker from 39CO14, known as both the Davis and Lower Grand site in Corson County, SD. Between 1968 and 1971, the human remains of this individual were transferred to William Bass at the University of Kansas. In 1971, Bass took the human remains to UTK. This individual is either an adolescent or a young adult female; the remains are highly fragmentary. No known individual was identified. No associated funerary objects are present.

In June 1969, human remains representing, at minimum, three individuals were removed from 39CO14, known as both the Davis and Lower Grand site in Corson County, SD. The principle investigator was W. Raymond Wood, and the excavations were directed by Carl R. Falk and Stanley A. Ahler under contract to the NPS. Between 1969 and 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is a newborn infant of indeterminate sex. The second and third individuals are both age and sex indeterminate due to their highly fragmentary nature. No known individuals were identified. The one associated funerary object is a container of sediment from the burial context of the first individual.

On July 28 and 29, 1969, human remains representing, at minimum, two individuals were removed by Marion Travis from 39CO14, known as both the Davis and Lower Grand site in Corson County, SD. Between 1969 and 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is an adult male, 40–44 years old. The second individual is an adult, probably male, 40+ years old. No known individuals were identified. No associated funerary objects are present.

Site 39CO14 comprises a fortified village. Archeological evidence places the site in the Extended Coalescent period (A.D. 1500–1675). Radiocarbon dating, with a 2-sigma probability range, places the site between A.D. 1449 and 1635 (Johnson 2007: 71). Anthropological, archeological and biological evidence support a finding that during the Extended Coalescent and Post Contact Coalescent periods, the people in this region were ancestral Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

In the summer of 1969, human remains representing, at minimum, 19 individuals were removed from 39CO31, 39CO32 or 39CO33, the Norvold sites, in Corson County, SD. William Bass directed the excavations. Post-excavation (likely in 1969), Bass took these skeletal remains to the University of Kansas. In 1971, Bass took these human remains to UTK. The human skeletal remains include two infants and four children, all of indeterminate sex, one female adolescent, 17–19 years old, and 12 adults. Of the adults, seven are probably male and five are probably female. No known individuals were identified. The 19 associated funerary objects include seven lots of botanicals, eight lots of fauna, two lots of glass, and two lots of minerals.

The Norvold sites (39CO31, 39CO32 and 39CO33) comprise a series of three earthlodge villages. Archeological evidence places them in the Extended Coalescent period (A.D. 1500–1675) or Post Contact Coalescent (A.D. 1675–

1780) periods. Anthropological, archeological and biological evidence support a finding that during the Extended Coalescent and Post Contact Coalescent periods the people in this region were ancestral Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Between 1968 and 1970, human remains representing, at minimum, 551 individuals were removed from 39WW1, the Mobridge site, in Walworth County, SD. William Bass excavated the Mobridge site and transferred the human remains to the University of Kansas. In 1971, Bass moved from the University of Kansas to UTK, and took the human remains with him. The skeletal remains belong to 317 infants and 61 children, all of indeterminate sex, 24 adolescents, and 149 adults. Of the adolescents, six are probably male, seven are probably female, and 11 are of indeterminate sex. Of the adults, 56 are probably male, 67 are probably female, and 26 are of indeterminate sex. No known individuals were identified. The 87 associated funerary objects include three lots of botanicals, 13 lots of ceramics, 55 lots of fauna, two lots of fossils, five lots of lithics, one lot of metal, seven lots of rock, and one lot of burial sediment.

At an unknown date, likely around the 1960s, human remains representing, at minimum, eight individuals were removed from 39WW1, the Mobridge site in Walworth County, SD, by Guy Gage and Jim Deis. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. One of the individuals is a child 8–12 years old. Another individual is an adolescent 9–15 years old. Both of them are of indeterminate sex. Six individuals are adults, of whom four are probably male, and two are probably female. No known individuals were identified. The 20 associated funerary objects are 19 faunal bones and one faunal tooth.

Located near the city of Mobridge on the eastern shore of Lake Oahe, site 39WW1 comprises an earthlodge village. It was first excavated in 1917, and has been described as an Arikara village. Additional archeological research on the material culture from the site places it within the Post-Contact Coalescent tradition, which is believed to be affiliated with the Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Between 1963 and 1964, human remains representing, at minimum, 81 individuals were removed from 39WW2, the Larson site, in Walworth County, SD, by Alfred Bowers of the River Basin Survey. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The skeletal remains belong to one infant and 15 children, all of indeterminate sex, 19 adolescents, and 46 adults. Of the adolescents, nine are probably males, four are probably female, and six are of indeterminate sex. Of the adults, 30 are probably male, 14 are probably female, and two are of indeterminate sex. No known individuals were identified. No associated funerary objects are present.

Around 1964, human remains representing, at minimum, two individuals were removed from 39WW2, the Larson site in Walworth County, SD, by unknown individuals. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is a child, 7–8 years old and of indeterminate sex. The second individual is an adolescent, 14–17 years old and possibly male. No known individuals were identified. The five associated funerary objects are faunal bones.

Around 1965, human remains representing, at minimum, two individuals were removed from 39WW2, the Larson site in Walworth County, SD, by David Evans and Richard Jantz. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. Both individuals are newborn infants. No known individuals were identified. No associated funerary objects are present.

Around 1966, human remains representing, at minimum, two individuals were removed from 39WW2, the Larson site in Walworth County, SD, by Robert Meyer and Mike Litschewski. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is an adult male, 25–30 years old. The second individual is an infant of indeterminate sex, newborn to 1.5 months old. No known individuals were identified. No associated funerary objects are present.

Around 1966, human remains representing, at minimum, six individuals were removed from 39WW2, the Larson site, in Walworth County, SD, by J.J. Hoffman of the River Basin Survey. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is an adult female, 40–45 years old. The second individual is an adult of indeterminate sex. The third individual is an adult female, 30–40 years old. The fourth individual is an infant, sex indeterminate, 1–2 years old. The fifth individual is an infant, sex indeterminate, 6–12 months old. The sixth individual is a female adult, 40+ years old. No known individuals were identified. No associated funerary objects are present.

Between 1966 and 1969, human remains representing, at minimum, 754 individuals were removed from 39WW2, the Larson site, in Walworth County, SD, by William Bass. Bass transferred the human remains to the University of Kansas. In 1971, Bass moved from Kansas to UTK, and took the human remains with him. The human remains belong to 411 infants and 100 children, all of indeterminate sex, 35 adolescents, and 208 adults. Of the adolescent individuals, six are probably male, 16 are probable female, and 13 are of indeterminate sex. Of the adults, 103 are probably male, 95 are probably female, and 10 are of indeterminate sex. No known individuals were identified. The 886 associated funerary objects include 108 lots of botanicals, 114 lots of ceramics, 378 lots of fauna, 89 lots of glass, 83 lots of lithics, 45 lots of metal, 22 lots of minerals, and 47 lots of rocks.

Around 1968, human remains representing, at minimum, one individual were removed from 39WW2, the Larson site in Walworth County, SD, by J.B. Gregg. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The individual is an adult female. No known individuals were identified. No associated funerary objects are present.

Around 1970, human remains representing, at minimum, three individuals were removed from 39WW2, the Larson site in Walworth County, SD, by Jones and P. Willey. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is an adult of indeterminate sex. The second individual is an infant of indeterminate sex, 1.5–3 months old. The third individual is an infant of indeterminate

sex, 1–1.5 years old. No known individuals were identified. No associated funerary objects are present.

At an unknown date, likely during the 1960s, human remains representing, at minimum, six individuals were removed from 39WW2, the Larson site in Walworth County, SD, by John Coleman and Marion Travis. Sometime prior to 1971, these human remains were transferred to William Bass at the University of Kansas. In 1971, Bass took these human remains to UTK. The first individual is an adolescent 14–19 years old, possibly male. The second individual is an infant of indeterminate sex, 1.5–2 years old. The third individual is an infant of indeterminate sex, 2.5–3 years old. The fourth individual is a female adult, 40+ years old. The fifth individual is an adolescent 16–20 years old, probably male. The sixth individual is an adult male, 40+ years old. No known individuals were identified. The four associated funerary objects are faunal bones.

Archeological evidence places the Larson site, 39WW2, in the Post-Contact Coalescent period, A.D. 1675–1780, with a suggested timeframe circa A.D. 1750–1780. Many excavations have taken place at this fortified village site, since the late 1890's, under the direction of L. De Lestry, W.H. Adams and W.H. Casler, W.H. Over, Alfred W. Bowers, J.J. Hoffman and William Bass. Anthropological, archeological and biological evidence support a finding that the people of the Extended Coalescent and Post Contact Coalescent periods in this region are ancestral Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

In 1956, human remains representing, at minimum, 49 individuals were removed from 39WW3, the Spiry-Eklo site, in Walworth County, SD, by David Baerreis, John Dallman and others from the University of Wisconsin, under the Inter-Agency Salvage Program in the Missouri Basin. Post-excavation, these human remains were presumably transferred to the University of Wisconsin. At an unknown date, likely between 1956 and the 1990s, the human remains were transferred from the University of Wisconsin to William Bass at UTK. The human remains include 26 infants and four children, all of indeterminate sex, one adolescent or young adult, probably female, and 18 adults. Of the adults, four are probably male, eight are probably female, and six are of indeterminate sex. No known individuals were identified. The 27 associated funerary objects include two lots of botanicals, two lots of ceramics, 21 lots of fauna, one lot of lithics, and one lot of minerals.

The Spiry-Eklo site, 39WW3, is located about a mile south of Mobridge, South Dakota. It comprises a village covering around 10 acres. The archeological evidence suggests that the major occupation of the site occurred during the Post Contact Coalescent Period (A.D. 1675–1780). Anthropological, archeological and biological evidence support a finding that the people of the earlier Extended Coalescent and the later Post Contact Coalescent periods are ancestral Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Between 1970 and 1972, human remains representing, at minimum, seven individuals were removed from 39WW203, the Walth Bay site, in Walworth County, SD. The principal investigator was W. Raymond Wood, and the excavations were directed by Carl R. Falk and Stanley A. Ahler, under contract to the NPS. Sometime after 1970, these human remains were transferred to William Bass. Individual 1 is an adult male, 40–45 years old. Individual 2 is a newborn infant of indeterminate sex. Individuals 3 and 4 are both infants, 1–3 years old and of indeterminate sex. Individual 5 is an adult male, 40–45 years old. Individual 6 is an adult male, 35–45 years old. Individual 7 is a young adult female. No known individuals were identified. The seven associated funerary objects are six faunal bones and one faunal tooth.

The Walth Bay site dates to the Extended Coalescent period (A.D. 1500–1675), based on the archeological evidence. Radiocarbon dating, with a 2-sigma probability range, dates the site between A.D. 1492 and 1653 (Johnson 2007: 72). Anthropological, archeological and biological evidence support a finding that the people of the Extended Coalescent and Post Contact Coalescent periods in this region are ancestral Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Based on morphological features, site and burial context, and associated funerary objects, UTK and the Omaha District have determined that the human remains in this Notice are of Native American ancestry. Additionally, based upon the historical record, anthropological and archeological evidence, site analysis, osteological analysis, and tribal consultation, UTK and the Omaha District have determined that there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Determinations Made by the University of Tennessee, Department of Anthropology and the U.S. Army Corps of Engineers, Omaha District

Officials of the University of Tennessee, Department of Anthropology and the U.S. Army Corps of Engineers, Omaha District have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 1,971 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 2,263 lots of objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Robert Hinde, University of Tennessee, Office of the Provost, 527 Andy Holt Tower, Knoxville, TN 37996–0152, telephone (865) 974–2445, email *rhinde@utk.edu and vpaa@utk.edu;* and Ms. Sandra Barnum, U.S. Army Engineer District, Omaha, ATTN: CENWO–PM–AB, 1616 Capital Avenue, Omaha, NE 68102, telephone (402) 995–2674, email *sandra.v.barnum@usace.army.mil,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota may proceed.

The University of Tennessee, Department of Anthropology and the U.S. Army Corps of Engineers, Omaha District are responsible for notifying the

Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota, that this notice has been published.

Dated: October 4, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24407 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029094; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Valley Authority, Knoxville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Tennessee Valley Authority (TVA) has completed an inventory of human remains in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the TVA. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the TVA at the address in this notice by December 9, 2019.

ADDRESSES: Dr. Thomas O. Maher, TVA, 400 West Summit Hill Drive, WT11C, Knoxville, TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Tennessee Valley Authority, Knoxville, TN. The human remains were removed from the Cox site, 1JA176, in Jackson County, AL.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by TVA professional staff in consultation with representatives of the Absentee-Shawnee Tribe Indians of Oklahoma; Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Alabama-Quassarte Tribal Town; Cherokee Nation; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Kialegee Tribal Town; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); Shawnee Tribe; The Chickasaw Nation; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma (hereafter referred to as ''The Consulted Tribes'').

History and Description of the Remains

The site listed in this notice was excavated as part of TVA's Guntersville Reservoir project by the Alabama Museum of Natural History (AMNH) at the University of Alabama, using labor and funds provided by the Works Progress Administration. Details regarding these excavations and sites may be found in a report, ''*An Archaeological Survey of Guntersville Basin on the Tennessee River in Northern Alabama,*'' by William S. Webb and Charles G. Wilder. Human remains and other associated funerary objects from this site were previously listed in a Notice of Inventory Completion published in the **Federal Register** on March 31, 2014 (79 FR 18056, March 31, 2014), and were transferred to The Muscogee (Creek) Nation. Additional human remains were found during a recent improvement in the curation of the TVA archeological collections at AMNH.

From April 27, 1938, to November 10, 1939, human remains representing, at minimum, one individual were removed from the Cox site, 1JA176, in Jackson County, AL. Excavation of the site commenced after TVA had acquired this land on July 19, 1937 for the Guntersville project. The site was composed of both a conical mound believed to have originally been a truncated pyramid with multiple stratigraphic zones, and a village containing most of the burial units. This site was occupied during the Woodland period (300 B.C.–A.D.1000) and the Crow Creek phase of the Mississippian period (ca. A.D. 1400–1600). No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Tennessee Valley Authority

Officials of the Tennessee Valley Authority have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on their presence in a prehistoric archeological site and osteological analysis.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.
- The Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma have declined to accept transfer of control of the human remains.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Muscogee (Creek) Nation.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Thomas O. Maher, TVA, 400 West Summit Hill Drive, WT11C, Knoxville, TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Muscogee (Creek) Nation may proceed.

The Tennessee Valley Authority is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: October 8, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24401 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029121; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Arkansas Archeological Survey, Fayetteville, AR; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Arkansas Archeological Survey has corrected an inventory of human remains published in a Notice of Inventory Completion in the **Federal Register** on December 22, 2014. This notice corrects the minimum number of individuals. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Arkansas Archeological Survey. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Arkansas Archeological Survey at the address in this notice by December 9, 2019.

ADDRESSES: Dr. George Sabo, Arkansas Archeological Survey, 2475 N Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556, email *gsabo@uark.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains under the control of the Arkansas Archeological Survey, Fayetteville, AR. The human remains were removed from Arkansas County, AR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the minimum number of individuals published in a Notice of Inventory Completion in the **Federal Register** (79 FR 76351–76361, December 22, 2014). Private individuals removed the human remains from Arkansas County in the 1930s and 1940s. These collections were acquired by the Joint Educational Consortium of Henderson State University and Ouachita Baptist University in 1977 and were transferred to the Arkansas Archeological Survey in 2017 to undergo the NAGPRA process. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (79 FR 76351, December 22, 2014), column 3, paragraph 7, sentence 1 is corrected by substituting the following sentence:

In the 1930s to 1940s and in 1979, human remains representing a minimum of two individuals were recovered from the Menard-Hodges site (3AR4) in Arkansas County, Arkansas.

In the **Federal Register** (79 FR 76351, December 22, 2014), column 3, paragraph 7, sentence 4 is corrected by substituting the following sentence:

Diagnostic artifacts found at the Menard-Hodges site (3AR4) indicate that these human remains were probably buried during the Menard Complex (late A.D. 1500) or the Protohistoric Period (A.D. 1500–1700)

In the **Federal Register** (79 FR 76361, December 22, 2014), column 3, paragraph 1, sentence 1 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 441 individuals of Native American Ancestry.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. George Sabo, Arkansas Archeological Survey, 2475 N Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556, email *gsabo@uark.edu,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Quapaw Tribe of Indians may proceed.

The Arkansas Archeological Survey is responsible for notifying The Quapaw Tribe of Indians that this notice has been published.

Dated: October 15, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24396 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029125; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Arkansas Archeological Survey, Fayetteville, AR; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Arkansas Archeological Survey has corrected an inventory of human remains published in a Notice of Inventory Completion in the **Federal Register** on February 24, 2017. This notice corrects the minimum number of individuals. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Arkansas Archeological Survey. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Arkansas Archeological Survey at the address in this notice by December 9, 2019.

ADDRESSES: Dr. George Sabo, Arkansas Archeological Survey, 2475 N Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556, email *gsabo@uark.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains under the control of the Arkansas Archeological Survey, Fayetteville, AR. The human remains were removed from Clark County, AR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of

the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the minimum number of individuals published in a Notice of Inventory Completion in the **Federal Register** (82 FR 11629–11631, February 24, 2017). Private individuals removed the human remains from Clark County in the 1930s and 1940s. These collections were acquired by the Joint Educational Consortium of Henderson State University and Ouachita Baptist University in 1977 and were transferred to the Arkansas Archeological Survey in 2017 to undergo the NAGPRA process. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (82 FR 11629, February 24, 2017), column 2, paragraph 7, sentence 1 is corrected by substituting the following sentence:

At an unknown date and between 1939–1940, human remains representing at minimum, two individuals were recovered from the East site (3CL21) in Clark County, Arkansas.

In the **Federal Register** (82 FR 11629, February 27, 2017), column 2, paragraph 7, sentence 4 is corrected by substituting the following sentence:

The one associated funerary object is a Smithport Plain jar.

In the **Federal Register** (82 FR 11629, February 24, 2017), column 2, paragraph 7, sentence 5 is corrected by substituting the following sentence:

Diagnostic artifacts found at the East site (3CL21) indicate that these human remains were probably buried during the Caddo tradition (A.D. 900–1650) or East Phase (A.D. 1100–1400).

In the **Federal Register** (82 FR 11631, February 24, 2017), column 2, paragraph 3, sentence 1 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 460 individuals of Native American ancestry.

In the **Federal Register** (82 FR 11631, February 24, 2017), column 2, paragraph 3, sentence 2 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001 (3)(A), the 55 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. George Sabo, Arkansas Archeological Survey, 2475 N Hatch Avenue, Fayetteville, AR 72704, telephone (479) 575–3556, email *gsabo@uark.edu,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Caddo Nation of Oklahoma may proceed.

The Arkansas Archeological Survey is responsible for notifying the Caddo Nation of Oklahoma that this notice has been published.

Dated: October 15, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24398 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029070; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: University of Tennessee, Department of Anthropology, Knoxville, TN, and U.S. Army Corps of Engineers, Omaha District, Omaha, NE

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of Tennessee, Department of Anthropology (UTK) and the U.S. Army Corps of Engineers, Omaha District (Omaha District), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to UTK and Omaha District. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to UTK and Omaha District at the address in this notice by December 9, 2019.

ADDRESSES: Dr. Robert Hinde, University of Tennessee, Office of the Provost, 527 Andy Holt Tower, Knoxville, TN 37996–0152, telephone (865) 974–2445, email *rhinde@utk.edu* and *vpaa@utk.edu.* Ms. Sandra Barnum, U.S. Army Engineer District, Omaha, ATTN: CENWO–PM–AB, 1616 Capital Avenue, Omaha, NE 68102, telephone (402) 995–2674, email *sandra.v.barnum@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the University of Tennessee, Department of Anthropology, Knoxville, TN, and the U.S. Army Corps of Engineers, Omaha District, Omaha, NE, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

During the summers of 1965 and 1966, 77 lots of cultural items were removed from 39CO9, the Leavenworth site, in Corson County, SD, under the direction of William Bass. After the excavations, Bass transferred the cultural items to the University of Kansas. In 1971 when he moved to Knoxville, Bass transferred the cultural items to UTK. The 77 lots of unassociated funerary objects include six lots of botanicals (wood and seeds), six lots of ceramics, seven lots of fauna (animal bones and hide), 33 lots of glass that include beads, two lots of lithics, 17 lots of metal items, and six lots of minerals.

The Leavenworth site dates to circa A.D. 1800 to 1832. It comprises a village and cemetery. The Leavenworth site is discussed in a number of historical documents, including those of French fur trader Pierre-Antoine Tabeau, who lived with the Arikara at the Leavenworth site, as well as in the Journals of Lewis and Clark, who visited the site in 1804. The site was attacked by Colonel Leavenworth in 1823. George Catlin passed the still-inhabited site on a steamboat in 1832. In 1834,

Maximilian, Prince of Wied, visited the Leavenworth site. Finding it abandoned, he collected some human remains. Excavation and removal of human remains and materials at the site continued during the twentieth century under the direction of various individuals, including W.H. Over, M.W. Stirling, W.D. Strong, J.B. Caldwell and William Bass. In addition to the historical documents stating that the Arikara inhabited the Leavenworth site, archeological research on the material culture from the site places it within the Post-Contact Coalescent tradition, which is believed to be affiliated with the Arikara. Today, the Arikara are part of the Mandan, Hidatsa and Arikara Nation, known as the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota. Consultation with the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota supports the definition of these objects as unassociated funerary objects. Bass did not collect the related human remains due to their fragmentary nature, but he did assign a burial number to the objects.

Determinations Made by the University of Tennessee, Department of Anthropology and the U.S. Army Corps of Engineers, Omaha District

Officials of the University of Tennessee, Department of Anthropology and the U.S. Army Corps of Engineers, Omaha District have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 77 lots of cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Dr. Robert Hinde, University of Tennessee, Office of the Provost, 527 Andy Holt Tower, Knoxville, TN 37996–0152, telephone (865) 974–2445, email *rhinde@utk.edu* and *vpaa@utk.edu;* and Ms. Sandra Barnum, U.S. Army Engineer District, Omaha, ATTN: CENWO–PM–AB, 1616 Capital Avenue, Omaha, NE 68102, telephone (402) 995–2674, email *sandra.v.barnum@usace.army.mil,* by December 9, 2019. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota may proceed.

The University of Tennessee, Department of Anthropology and the U.S. Army Corps of Engineers, Omaha District are responsible for notifying the Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota, that this notice has been published.

Dated: October 4, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24409 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0029074; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, San Jose State University, San Jose, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology at San Jose State University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Department of Anthropology, San Jose State University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Department of Anthropology, San Jose State University at the address in this notice by December 9, 2019.

ADDRESSES: Charlotte Sunseri (NAGPRA Coordinator), San Jose State University, Department of Anthropology, Clark Hall 469, 1 Washington Square, San Jose, CA 95192–0113, telephone (408) 924–5710, email *charlotte.sunseri@sjsu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Department of Anthropology, San Jose State University, San Jose, CA. The human remains and associated funerary objects were removed from site CA–STA–133, Stanislaus County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, San Jose State University professional staff in consultation with representatives of the Picayune Rancheria of Chukchansi Indians of California; Santa Rosa Indian Community of the Santa Rosa Rancheria, California; Table Mountain Rancheria (previously listed as the Table Mountain Rancheria of California); Tejon Indian Tribe; and the Tule River Indian Tribe of the Tule River Reservation, California (hereafter referred to as ''The Tribes'').

History and Description of the Remains

In 1962–1963, human remains representing, at minimum, two individuals were removed from CA–STA–133 in Stanislaus County, CA. The site was excavated by Leonard J. Foota and San Francisco State University affiliates in 1962, and the human remains were under the control of San Francisco State University until they were donated to San Jose State University on February 15, 1963. The

human remains comprise the nearly complete skeleton of a 45 year-old female and a partial skeleton of an unknown individual. The two associated funerary objects are shell beads.

Based on the geographic location of the site within this tribe's historically documented territory, these human remains have been determined to be culturally affiliated with The Tribes.

Determinations Made by the Department of Anthropology, San Jose State University

Officials of the Department of Anthropology, San Jose State University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the two objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Charlotte Sunseri (NAGPRA Coordinator), Department of Anthropology, San Jose State University, Clark Hall 469, 1 Washington Square, San Jose, CA 95192–0113, telephone (408) 924–5710, email *charlotte.sunseri@sjsu.edu,* by December 9, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Department of Anthropology, San Jose State University is responsible for notifying The Tribes that this notice has been published.

Dated: October 4, 2019.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–24394 Filed 11–7–19; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1182]

Certain Argon Plasma Coagulation System Probes, Their Components, and Other Argon Plasm Coagulation System Components for Use Therewith; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 7, 2019, under section 337 of the Tariff Act of 1930, as amended, on behalf of Erbe Elektromedizin GmbH of the Republic of Germany and Erbe USA, Inc. of Marietta, Georgia. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain argon plasma coagulation system probes, their components, and other argon plasma coagulation system components for use therewith by reason of infringement of certain claims of U.S. Patent No. 7,311,707 (''the '707 patent''); U.S. Patent No. 7,717,911 (''the '911 patent''); U.S. Patent No. 9,510,889 (''the '889 patent''); U.S. Patent No. 9,603,653 (''the '653 patent''); and U.S. Patent No. D577,671 (''the '671 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained 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 at *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.*

FOR FURTHER INFORMATION CONTACT: Pathenia Proctor, Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2019).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 4, 2019, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1 and 5–8 of the '707 patent; claims 1, 3–6, and 9 of the '911 patent; claims 1–10, 14, 16–22, and 24–27 of the '889 patent; claims 1–3, 5, 6, 8–10, 13, 14, and 16 of the '653 patent; and the claim of the '671 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''argon plasma coagulation (''APC'') probes for use in endoscopic procedures, their components, and other APC system components for use with those probes'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Erbe Elektromedizin GmbH, Waldhörnlestrasse 17, 72072 Tübingen, Republic of Germany

Erbe USA, Inc., 2225 Northwest Parkway, Marietta, GA 30067

(b) The respondents are the following entities alleged to be in violation of section 337, and is/are the parties upon which the complaint is to be served:

Olympus Corporation, Shinjuku Monolith, 3–1 Nishi-Shinjuku 2-

chome, Shinjuku-ku, Tokyo 163–0914, Japan
Olympus Corporation of the Americas, 3500 Corporate Parkway, Center Valley, PA 18034–0610
Olympus America, Inc., 3500 Corporate Parkway, Center Valley, PA 18034–0610
Olympus Surgical Technologies Europe, Kuehnstrasse 61, 22045 Hamburg, Republic of Germany
Olympus Winter & lbe GmbH, Kuehnstrasse 61, 22045 Hamburg Republic of Germany
Olympus KeyMed Group Limited, KeyMed House, Stock Road, Southend-on-Sea, ESSEX, SS2 5QH, United Kingdom
KeyMed (Medical & Industrial Equipment) Ltd., KeyMed House, Stock Road, Southend-on-Sea, ESSEX, SS2 SQH, United Kingdom
Olympus Bolton, 18 Queensbrook, BOLTON, BL1 4AY, United Kingdom
Olympus Surgical Technologies Europe | Cardiff, Fortran Road, St. Mellons, CARDIFF, CF3 0LT, United Kingdom

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 4, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–24371 Filed 11–7–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1130]

Certain Beverage Dispensing Systems and Components Thereof; Commission Decision To Review a Final Initial Determination in Its Entirety; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has determined to review the presiding administrative law judge's (''ALJ's'') final initial determination (''ID'' or ''final ID'') finding a violation of section 337 of the Tariff Act of 1930, as amended, with respect to U.S. Patent No. 7,188,751 (''the '751 patent''). The Commission requests briefing from the parties on certain issues under review, as set forth in this notice. The Commission also requests briefing from the parties, interested persons, and government agencies on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2532. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server (*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.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 5, 2018, based on a complaint filed by Heineken International B.V. and Heineken Supply Chain B.V., both of Amsterdam, The Netherlands; and Heineken USA Inc. of White Plains, New York (collectively, ''Heineken''). 83 FR 45141, 45141–42 (Sept. 5, 2019). The complaint alleges a violation of 19 U.S.C. 1337 in the importation into the United States, sale for importation, or sale in the United States after importation of certain beverage dispensing systems and components thereof that allegedly infringe claims 1–11 of the '751 patent. *Id.* The notice of investigation names as respondents Anheuser-Busch InBev SA, and InBev Belgium NV, both of Leuven, Belgium; and Anheuser-Busch, LLC of St. Louis, Missouri (collectively, ''ABI''). *Id.* The Office of Unfair Import Investigations was not named as a party to this investigation. *Id.*

On February 6, 2019, the ALJ granted Heineken's motion to partially terminate the investigation as to claims 2, 4–6, 8–9, and 11 of the '751 patent. Order No. 6 (Feb. 6, 2019), *not reviewed,* Notice (Mar. 7, 2019). Remaining within the investigation are claims 1, 3, 7, and 10 of the '751 patent. On March 26, 2019, the ALJ issued Order No. 14, the *Markman* Order, construing certain claim terms. The ALJ conducted the evidentiary hearing from April 16–18 and 23, 2019.

On September 5, 2019, the ALJ issued the subject final ID, finding claims 1, 3, 7, and 10 infringed and not invalid, and thereby finding a violation of section 337. On September 19, 2019, the ALJ issued a Recommended Determination on Remedy and Bond (''RD''). The RD recommends that should the Commission find a violation of section 337, that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond rate during the period of Presidential review in the amount of 5% of the entered value of infringing articles.

On September 18, 2019, ABI filed a petition for Commission review of the ID. That same day, Heineken filed a contingent petition for review. On September 26, 2019, the parties responded to each other's petitions.

Having reviewed the record of the investigation, including Order No. 14, the final ID, and the parties' submissions to the ALJ and to the Commission, the Commission has determined to review the ID in its entirety.

In connection with its review, the Commission requests responses to the following questions. The parties are

requested to brief their positions with reference to the applicable law and the existing evidentiary record.[1]

(1) If the Commission were to find that the ''operating element'' limitation of claims 1 and 7 should be construed as a means-plus-function claim limitation, and if the Commission were to adopt Heineken's recited function and corresponding structure as set forth on pages 12–13 of Claim Chart No. 1 in Order No. 14:

Whether the accused products and domestic industry products practice that limitation.

The parties are not to provide further briefing as to the propriety of such a construction, or to advocate alternative claim constructions. The existing record is adequate as to the parties' positions on these issues.

(2) Whether, for purposes of contributory infringement under 35 U.S.C. 271(c), the accused NOVA couplers or the NOVA appliances are especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

(3) Whether claims 1 and 7 of the '751 patent are obvious in view of Figures 17–20 and the associated written description in Jeans (RX–658) (*see* ABI Pet. for Comm'n Rev. at 50–54) when combined with Timmermans (RX–838), van der Meer (RX–837) or Grill (RX–312).

(4) Whether Heineken demonstrated significant investment in plant and equipment or significant employment of labor or capital, *see* 19 U.S.C. 1337(a)(3)(A), (B), in an appropriate context, in view of Federal Circuit and Commission precedent concerning such context (including but not limited to *Certain Carburetors and Products Containing Such Carburetors,* Inv. No. 337–1123, Comm'n Op. (Oct. 28, 2019) (public version)). For any context you argue is appropriate, please address the evidence in the record that permits an analysis within that context.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions limited to the enumerated questions above. The parties' opening submissions should not exceed 50 pages, and their reply submissions should not exceed 40 pages. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the date that the asserted patents expire and the HTSUS numbers under which the accused products are imported, and provide identification information for all known importers of the subject articles. Initial written submissions and proposed remedial orders must be filed no later than close of business on Monday, November 18, 2019. Reply submissions must be filed no later than the close of business on Tuesday, November 26, 2019. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (Inv. No. 337–TA–1130) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary at (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract

[1] In reviewing the ID, and in seeking briefing on these issues, the Commission has not determined to excuse any party's noncompliance with Commission rules and the ALJ's procedural requirements, including requirements to present issues in pre-hearing and post-hearing submissions. *See, e.g.,* Order No. 3 (Sept. 11, 2018) (ground rules). The Commission may, for example, decline to disturb certain findings in the final ID upon finding that issue was not presented in a timely manner to the ALJ.

personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 4, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–24369 Filed 11–7–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Numerical Propulsion System Simulation

Notice is hereby given that, on September 11, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute —Cooperative Research Group on Numerical Propulsion System Simulation (''NPSS'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Honda R&D Co., Ltd., Saitama, JAPAN, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NPSS intends to file additional written notifications disclosing all changes in membership.

On December 11, 2013, NPSS filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 20, 2014 (79 FR 9767).

The last notification was filed with the Department on January 27, 2016. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 9, 2016 (81 FR 12528).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–24437 Filed 11–7–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0020]

Additional Requirements for Special Dipping and Coating Operations (Dip Tanks); Extension of the Office of Management and Budget's (OMB) Approval of the Information Collection (Paperwork) Requirement

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget (OMB) approval of the information collection requirement specified in the Standard on Dipping and Coating Operations (Dip Tanks).

DATES: Comments must be submitted (postmarked, sent, or received) by January 7, 2020.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA–2010–0020, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the OSHA Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2010–0020) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security number and date of birth are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney or Seleda Perryman at (202) 693–2222 to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone: (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of a continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, the reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (see 29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with a minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining said information (see 29 U.S.C. 657).

[2] All contract personnel will sign appropriate nondisclosure agreements.

The Standard on Dipping and Coating Operations (29 CFR 1910.126(g)(4)) requires employers to post a conspicuous sign near each piece of electrostatic detearing equipment that notifies employees of the minimum safe distance they must maintain between goods undergoing electrostatic detearing and the electrodes or conductors of the equipment used in the process. Doing so reduces the likelihood of igniting the explosive chemicals used in electrostatic detearing operations.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirement is necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirement, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The agency is requesting to retain the previous burden hour estimate of one (1) hour. There are no program changes or adjustments associated with the information collection requirement in the Standard. The agency has correspondingly adjusted the per response burden to maintain a time burden as close as is possible to the actual time of no hours (1 hour). OSHA is requesting that OMB extend approval of the information collection requirement contained in the Standard on Additional Requirements for Special Dipping and Coating Operations (Dip Tanks) (29 CFR 1910.126(g)(4)). This provision requires the employer to determine how far away goods being electrostatically deteared should be separated from electrodes or conductors, is called the ''safe distance.'' This minimum distance must be displayed conspicuously on a sign located near the equipment.

OSHA has determined that where electrostatic equipment is being used, the information has already been ascertained and that the ''safe distance'' has been displayed on a sign in a permanent manner. The agency will summarize the comments submitted in response to this notice, and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved information collection.

Title: Additional Requirements for Special Dipping and Coating Operations (Dip Tanks) (29 CFR 1910.126(g)(4)).

OMB Control Number: 1218–0237.

Affected Public: Business or other for-profits; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 10.

Frequency of Recordkeeping: On occasion.

Total Responses: 10.

Average Time per Response: 0.

Estimated Total Burden Hours: 1.

Estimated Cost (Operation and Maintenance). $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number (Docket No. OSHA–2010–0020) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 1, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–24373 Filed 11–7–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0862]

Hazardous Wastes Operations and Emergency Response (HAZWOPER) Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by January 7, 2020.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When

using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA–2011–0862, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2011–0862) for the Information Collection Request (ICR). All comments, including any personal information you provide such as social security numbers and date of births, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You also may contact Theda Kenney or Seleda Perryman at (202) 693–2222 to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of a continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, the reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (see 29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with a minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining said information (see 29 U.S.C. 657).

The Hazardous Waste Operations and Emergency Response Standard (29 CFR 1910.120) specifies a number of collection of information (paperwork) requirements. Employers can use the information collected under the HAZWOPER rule to develop the various programs the Standard requires and to ensure that their workers are trained properly about the safety and health hazards associated with hazardous waste operations and emergency response to hazardous waste releases. OSHA will use the records developed in response to this Standard to determine adequate compliance with the Standard's safety and health provisions. The employer's failure to collect and distribute the information required in this standard will affect significantly OSHA's effort to control and reduce injuries and fatalities. Such failure would also be contrary to the direction Congress provided in Superfund Amendments and Reauthorization Act (SARA).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the collection of information (paperwork) requirements contained in the Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard. OSHA is requesting an adjustment decrease of 1,256 burden hours from the previous submission (from 261,551 hours to 260,295 hours).

The agency will summarize any comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard (29 CFR 1910.120).

OMB Number: 1218–0202.

Affected Public: Business or other for-profits; Not-for-profit organizations; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 29,727.

Frequency of Response: Business or other for-profits; Not-for-profit organizations; Federal Government; State, Local, or Tribal Government.

Total Responses: 1,468,062.

Average Time per Response: Various.

Estimated Total Burden Hours: 260,295.

Estimated Cost (Operation and Maintenance): $10,127,325.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number (Docket No. OSHA–2011–0862) for this ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 1, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–24374 Filed 11–7–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Extension of Existing Collections; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Claim for Compensation by Dependents Information Reports (CA–5, CA–5b, CA–1031, CA–1074, Letter of Compensation Due at Death, and Letter of Student/Dependency). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before January 7, 2020.

ADDRESSES: You may submit comments by mail, delivery service, or by hand to Anjanette Suggs, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210; by fax, (202) 354–9660, or email to *suggs.anjanette@dol.gov.* Please use only one method of transmission for comments (mail or email).

SUPPLEMENTARY INFORMATION: I. *Background:* The forms included in this package are forms used by Federal employees and their dependents to claim benefits, to prove continued eligibility for benefits, to show entitlement to remaining compensation payments of a deceased employee and to show dependency under the Federal Employees' Compensation Act. There are six items in this information collection request. The information collected by Forms CA–5, is used by dependents for claiming compensation for the work related death of a Federal Employee and CA–5b is used by other survivors. Form CA–1031 is used in disability cases and provides information to determine whether a claimant is actually supporting a dependent and is entitled to additional compensation. Form CA–1074 is a follow up to CA–5b to request clarification of any information that is unclear and incomplete in the CA–5b. The letter of ''Compensation Due at Death'' is used to request information necessary to distribute compensation due when an employee dies who was receiving or who was entitled to compensation at the time of death for either disability benefits or a scheduled award. The letter of ''Student/Dependency'' is used to obtain information regarding the student status of a dependent. When a child reaches 18 years of age, they are no longer considered an eligible dependent unless they are a full time student or incapable of self-support. This information collection is currently approved for use through August 31, 2016.

II. *Review Focus:* The Department of Labor is particularly interested in comments which:

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

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. *Current Actions:* The Department of Labor seeks extension of approval to collect this information in order to carry out its responsibility to meet the statutory requirements of the Federal Employees' Compensation Act. The information contained in these forms is used by the Division of Federal Employees' Compensation to determine entitlement to benefits under the Act, to verify dependent status, and to initiate, continue, adjust, or terminate benefits based on eligibility criteria.

Type of Review: Extension.

Agency: Office of Workers' Compensation Programs.

Title: Claim for Compensation by Dependents Information Reports.

OMB Number: 1240–0013.

Agency Number: CA–5, CA–5b, CA–1031, CA–1074, Letter of Compensation Due at Death, and Letter of Student/Dependency.

Affected Public: Individuals or households.

Total Respondents: 933.

Total Responses: 933.

Form/letter	Time to complete (minutes)	Frequency of response	Number of respondents	Hours burden
CA–5/5b	90	1	333	500
CA–1031	20	1	38	13
CA–1074	60	1	10	10
Student Dependency	30	1	299	150
Comp Due at Death	30	1	253	127
Totals			933	800

Estimated Total Burden Hours: 800.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $541.

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

Ajanette Suggs,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2019–24359 Filed 11–7–19; 8:45 am]

BILLING CODE 4510–CH–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request; Security Program

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following extension of a currently approved collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before January 7, 2020 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Mackie Malaka, National Credit Union Administration, 1775 Duke Street, Suite 6060, Alexandria, Virginia 22314; Fax No. 703–519–8579; or email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to Mackie Malaka at the address above or telephone 703–548–2704.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0033.

Title: Security Program, 12 CFR part 748.

Form: None.

Type of Review: Extension of a currently approved collection.

Abstract: In accordance with Title V of the Gramm-Leach-Bliley Act (15 U.S.C. 6801 *et seq.*), as implemented by 12 CFR part 748, federally-insured credit unions (FICU) are required to develop and implement a written security program to safeguard sensitive member information. This information collection requires that such programs be designed to respond to incidents of unauthorized access or use, in order to prevent substantial harm or serious inconvenience to members.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Number of Respondents: 5,308.

Estimated Number of Responses per Respondent: 30.

Estimated Total Annual Responses: 159,240.

Estimated Burden Hours per Response: 2.0.

Estimated Total Annual Burden Hours: 318,480.

Reason for Change: Adjustments have been made to the current number of FICUs based on the June call report to 5308. NCUA has also revised the number of responses per respondent (frequency) and adjusted the times where necessary to reflect a more accurate accounting of the burden associated with this reporting and recordkeeping requirement.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) Whether the collection of information is necessary for the proper execution of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on November 5, 2019.

Dated: November 5, 2019.

Mackie I. Malaka,

NCUA PRA Clearance Officer.

[FR Doc. 2019–24432 Filed 11–7–19; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Submission for OMB Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice.

DATES: Comments should be received on or before December 9, 2019 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) NCUA PRA Clearance Officer, 1775 Duke Street, Suite 6060, Alexandria, VA 22314, or email at *PRAComments@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Mackie Malaka at (703) 548–2704, emailing *PRAComments@ncua.gov,* or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0032.

Type of Review: Extension currently approved collection.

Title: Records Preservation, 12 CFR part 749.

Abstract: Part 749 of the NCUA Regulations directs each credit union to have a vital records preservation program that includes procedures for maintaining duplicate vital records at a location far enough from the credit union's offices to avoid the simultaneous loss of both sets of records in the event of disaster. Part 749 also requires the program be in writing and include emergency contact information for employees, officials, regulatory offices, and vendors used to support vital records.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated No. of Respondents: 5,308.

Estimated No. of Responses per Respondent: 12.

Estimated Total Annual Responses: 63,696.

Estimated Hours per Response: 2.

Estimated Total Annual Burden Hours: 127,392.

Reason for Change: The number of respondents have been updated to reflect the current number of FICUs of the June call report to 5,308. The number of responses per respondent (frequency) have been revised to include the monthly maintenance of the FICU's recordkeeping requirements under this part.

By Gerard Poliquin, Secretary of the Board, the National Credit Union Administration, on November 4, 2019.

Dated: November 4, 2019.

Mackie I. Malaka,

NCUA PRA Clearance Officer.

[FR Doc. 2019–24355 Filed 11–7–19; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces its intent to hold proposal review meetings throughout the year. The purpose of these meetings is to provide advice and recommendations concerning proposals submitted to the NSF for financial support. The agenda for each of these meetings is to review and evaluate proposals as part of the selection process for awards. The review and evaluation may also include assessment of the progress of awarded proposals. These meetings will primarily take place at NSF's headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314.

These meetings will be closed to the public. The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act. NSF will continue to review the agenda and merits of each meeting for overall compliance of the Federal Advisory Committee Act.

These closed proposal review meetings will not be announced on an individual basis in the **Federal Register**. NSF intends to publish a notice similar to this on a quarterly basis. For an advance listing of the closed proposal review meetings that include the names of the proposal review panel and the time, date, place, and any information on changes, corrections, or cancellations, please visit the NSF website: *https://www.nsf.gov/events/advisory.jsp.* This information may also be requested by telephoning, 703/292–8687.

Dated: November 4, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–24358 Filed 11–7–19; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Computing and Communication Foundations; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

NAME AND COMMITTEE CODE: Proposal Review Panel for Computing and Communication Foundations (#1192)—CSoI (Purdue University) Reverse Site Visit.

DATE AND TIME: December 11, 2019; 8:00 a.m.–5:00 p.m.

PLACE: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

TYPE OF MEETING: Part-Open.

CONTACT PERSON: Phillip Regalia, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: (703) 292–8910.

PURPOSE OF MEETING: Reverse site visit to assess the progress of the STC Award: CCF–0939370, ''Emerging Frontiers of Science of Information'', and to provide advice and recommendations concerning further support for the project.

Agenda

Wednesday, December 11, 2019; 8:00 AM–5:00 PM

8:00 a.m. to 3:00 p.m.: Open

Presentations by Awardee Institution, faculty staff and students to Site Team and NSF Staff. Discussions, questions and answer sessions.

3:00 p.m.–5:00 p.m.: Closed

Response and feedback to presentations by Site Team and NSF Staff. Discussions, questions and answer sessions. Draft report on education and research activities. Complete written site visit report with preliminary recommendations.

Reason for Closing: The work being reviewed during closed portions of the reverse site review include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the review. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 5, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–24408 Filed 11–7–19; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 11, 18, 25, December 2, 9, 16, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of November 11, 2019

Wednesday, November 13, 2019

9:00 a.m. Briefing on Security Issues (Closed Ex. 1)

Week of November 18, 2019—Tentative

There are no meetings scheduled for the week of November 18, 2019.

Week of November 25, 2019—Tentative

There are no meetings scheduled for the week of November 25, 2019.

Week of December 2, 2019—Tentative

Wednesday, December 4, 2019

9:00 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines (Public Meeting) (Contact: Damaris Marcano: 301–415–7328)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Friday, December 6, 2019

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public Meeting) (Contact: Larry Burkhart: 301–287–3775)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 9, 2019—Tentative

There are no meetings scheduled for the week of December 9, 2019.

Week of December 16, 2019—Tentative

Tuesday, December 17, 2019

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting) (Contact: Larniece McKoy Moore: 301–415–1942)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated at Rockville, Maryland, this 6th day of November 2019.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2019–24515 Filed 11–6–19; 11:15 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0270, Assignment, Federal Employees' Group Life Insurance (FEGLI) Program, RI 76–10

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request RI 76–10, Assignment, Federal Employees' Group Life Insurance (FEGLI) Program.

DATES: Comments are encouraged and will be accepted until December 9, 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, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0270) was previously published in the **Federal Register** on April 17, 2019 at 84 FR 16050, allowing for a 60-day public comment period. No comments were received for this collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

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

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

RI 76–10 allows an insured individual to transfer ownership, or ''assign'' the FEGLI coverage, to a third party. An insured may assign for several reasons; for example, for financial planning purposes, or to comply with a court order, or to sell the coverage to a third-party. Unlike a designation of beneficiary, once an assignment is executed, it is irrevocable.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Assignment, Federal Employees' Group Life Insurance (FEGLI) Program.

OMB Number: 3206–0270.

Frequency: Annually.

Affected Public: Federal employees, retirees, and assignees.

Number of Respondents: 400.

Estimated Time per Respondent: 15 minutes.

Total Burden Hours: 100 hours.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2019–24370 Filed 11–7–19; 8:45 am]

BILLING CODE 6325–38–P

RAILROAD RETIREMENT BOARD

Sunshine Act Meetings

TIME AND DATE: 10 a.m., November 20, 2019.

PLACE: 8th Floor Board Conference Room, 844 North Rush Street, Chicago, Illinois 60611.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

1. Oversight of the National Railroad Retirement Investment Trust
2. Update from the SCOTUS Working Group
3. Fraud Risk Assessment Committee proposal
4. Ninety day deferral (Concurrent processing of an application for a disability annuity)
5. Update on Chief Medical Officer search

CONTACT PERSON FOR MORE INFORMATION: Stephanie Hillyard, Secretary to the Board, Phone No. 312–751–4920.

Authority: 5 U.S.C. 552b.

Dated: November 6, 2019.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2019–24595 Filed 11–6–19; 4:15 pm]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:

Rule 15Fi–2—Trade Acknowledgment and Verification of Security-Based Swap Transactions; SEC File No. 270–633, OMB Control No. 3235–0713.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17Ad–22 (17 CFR 240.17Ad–22) under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15Fi–2 requires security-based swaps (''SBS'') dealers and major SBS participants (collectively, ''SBS Entities'') to provide to their counterparties a trade acknowledgment, to provide prompt verification of the terms provided in a trade acknowledgment of transactions from other SBS Entities, and to have written policies and procedures that are reasonably designed to obtain prompt verification of the terms provided in a trade acknowledgment. The Rule promotes the efficient operation of the SBS market and facilitate market participants' management of their SBS-related risk.

The Commission estimates that approximately 50 entities fit within the definition of SBS dealer, and up to five entities fit within the definition of major SBS participant. Thus, we expect that approximately 55 entities will be required to register with the Commission as SBS Entities and will be subject to the trade acknowledgment provision and verification requirements of Rule 15Fi-2. The total estimated annual burden of Rule 15Fi-2 is 34,155 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (b) the accuracy of the Commission staff's estimates of the burden of the proposed collection of information; (c) the ways to enhance the quality, utility, and clarity of the information 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 in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 5, 2019.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24418 Filed 11–7–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Small Business Capital Formation Advisory Committee on Small and Emerging Companies will hold a public meeting on Tuesday, November 12, 2019 at 9:30 a.m.

PLACE: The meeting will be held in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will begin at 9:30 a.m. (ET) and will be open to the public. Seating will be on a first-come, first-served basis. Doors will open at 9 a.m. Visitors will be subject to security checks. The meeting will be webcast on the Commission's website at *www.sec.gov.*

MATTERS TO BE CONSIDERED: On November 1, 2019, the Commission published notice of the Committee meeting (Release No. 33–10724), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: November 5, 2019.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2019–24500 Filed 11–6–19; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87455; File No. SR–CBOE–2019–102]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend the Fat Finger Check in Rule 5.34 as It Applies to Stop-Limit Orders

November 4, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the

''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 29, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the fat finger check in Rule 5.34 as it applies to Stop-Limit orders. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fat finger check under Rule 5.34(c)(1) as it applies to Stop-Limit orders. Currently, Rule 5.34(c)(1) provides that if a User submits a buy (sell) limit order to the System with a price that is more than a buffer amount above (below) the NBO (NBB), the System cancels or rejects the order (*i.e.,* the ''fat finger'' check). The Exchange determines a default buffer amount; however, a User may establish a higher or lower amount than the Exchange default. This check generally applies to orders and quotes with a limit price, subject to certain exceptions set forth in current Rules 5.34(c)(1)(B) through (D). For example, current Rule 5.34(c)(1)(D) provides that the check does not apply to bulk messages.[5]

The Exchange proposes to add Stop-Limit orders to Rule 5.34(c)(1)(D) as an additional order type to which the fat finger check does not apply. A ''Stop-Limit'' order is an order to buy (sell) that becomes a limit order when the consolidated last sale price (excluding prices from complex order trades if outside the NBBO) or NBB (NBO) for a particular option contract is equal to or above (below) the stop price specified by the User.[6] Stop-Limit orders allow Users increased control and flexibility over their transactions and the prices at which they are willing to execute an order. The purpose of a Stop-Limit order is to not execute upon entry, and instead rest in the System until the market reaches a certain price level, at which time the order could be executed. As such, when a buy (sell) Stop-Limit order is activated, its limit price may likely be outside of the buffer amount above (below) the NBO (NBB) in anticipation of capturing rapidly increasing (decreasing) market prices.

The primary purpose of the fat finger check is to prevent limit orders from executing at potentially erroneous prices upon entry, because the limit prices are ''too far away'' from the then-current NBBO. As noted above, a Stop-Limit order is not intended to execute upon entry. Currently, because a Stop-Limit order does not ''become'' a limit order until activated, the limit order fat finger check applies to a Stop-Limit order at the time the order is activated. As noted above, at that time, the limit price may cross the NBO, and thus may be cancelled due to the fat finger check if the limit price crosses the NBO by more than the buffer. Therefore, the manner in which the fat finger check cancels/rejects a Stop-Limit order may conflict with the intended purpose of a Stop-Limit order and a User's control over the time when and the price at which it executes. For example, assume that when the NBBO is 8.00 x 8.05, a User submits a Stop-Limit order to buy at 9.25 and a stop price of 8.15 and the User has set the fat finger buffer to $1.00. Assume the NBBO then updates to 8.15 x 8.20. The updated NBB equals the stop price of the order will activate the stop price of the Stop Limit Order, converting it into a limit order to buy at 9.25, which would be more than the fat finger buffer of $1.00 above the current NBO, thus canceled/rejected by the System in accordance with the fat finger check. The Exchange also notes that the System is currently able to apply only one buffer amount (either the Exchange default amount or a User's established amount) across multiple order types. Therefore, a User would not be able to expand the buffer amount to accommodate Stop-Limit orders without potentially over-expanding the buffer amount for other limit orders that execute upon entry.

The Exchange notes that a User's Stop-Limit orders would still be subject to other price protections already in place on the Exchange. In particular, Rule 5.32(c)(2) specifically applies to Stop-Limit orders and provides that the System cancels or rejects a buy (sell) Stop-Limit order if the NBB (NBO) at the time the System receives the order is equal to or above (below) the stop price.[7] Because the purpose of a Stop-Limit order is to rest in the Book until a specified price is reached, the Exchange believes rejecting a stop or stop-limit order entered above or below, as applicable, that price may be erroneous, as entry at that time would be inconsistent with the purpose of the order. Additionally, drill-through protections are in place pursuant to Rule 5.34(a)(4), such that, if a buy (sell) order would execute (*i.e.,* when the stop price for a Stop-Limit order is activated), the System executes the order up to a buffer amount (the Exchange determines the amount on a class and premium basis) above (below) the NBO (NBB) that existed at the time of order entry (''the drill-through price'').

The Exchange believes that allowing a Stop-Limit order, once activated, with a limit price outside of the NBBO (notwithstanding any fat finger buffer) to execute at that limit price (up to the drill-through buffer amount) is consistent with the intended purpose of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange notes that a separate provision governs a fat finger check specific to bulk messages. *See* Rule 5.34(a)(5).

[6] *See* Rule 5.6(c) (definition of Stop-Limit order).

[7] However, the System accepts a buy (sell) Stop-Limit order if the consolidated last sale price at the time the System receives the order is equal to or above (below) the stop price. The Exchange notes that the System is unable to compare the stop price of a stop-limit order to the last consolidated sale price upon receipt of the order, which is why the order is accepted when the stop price is above (below) the last consolidated sale price when the System receives it.

a Stop-Limit order. As stated, when a buy (sell) Stop-Limit order is activated, its limit price is intended to be at a consequential amount above (below) the NBO (NBB) in order to capture rapidly increasing (decreasing) trade prices, to which the NBBO would as rapidly track and reflect. To cancel or reject such orders based on the NBBO at the time of its activation would inhibit Stop-Limit orders from capturing favorable trade prices as a result of a rapidly shifting market.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change benefits market participants by ensuring that they are able to use Stop-Limit orders to achieve their intended purpose. As stated, Stop-Limit orders are intended to increase User price control and flexibility, particularly in the face of price swings and market volatility, by resting in the System until the market reaches a certain price level. Thus, they are not intended to execute upon entry. Conversely, the primary purpose of the fat finger check is to prevent limit orders from executing at potentially erroneous prices upon entry, because the limit prices are ''too far away'' from the then-current NBBO. By excluding Stop-Limit orders from the fat finger check, which would currently cancel/reject a Stop-Limit order if its buy (sell) limit price was above (below) the NBO (NBB) upon activation of its stop limit price, the proposed rule change removes impediments to and perfects the mechanism of a free and open market and national market system by allowing Users the control and flexibility to set the limit prices on Stop-Limit orders so as to capture significant market fluctuations, which, as stated, result in corresponding significant adjustments in the NBBO. Therefore, the proposed rule change is designed to protect investors by allowing their Stop-Limit orders to execute as intended without being canceled or rejected in connection with the NBBO that existed at the time of their activation, and instead to consider rapid price movements and corresponding NBBO adjustments. The Exchange notes that the proposed rule change will not affect the protection of investors or the maintenance of a fair and orderly market because other price controls would apply to Stop-Limit orders, both at the time of their submission and when their stop prices are activated and they become limit orders.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because all Users' Stop-Limit orders will be excluded from the fat finger check in the same manner. Also, all Users' Stop-Limit orders will continue to be subject to other specific price controls in place, both at the time of their submission and once their stop prices are activated and they become limit orders. The proposed rule change will not impose any burden on intermarket competition that that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change is merely designed to allow Users' Stop-Limit orders to execute in a manner that achieves their intended purpose by updating a price protection mechanism already in place on the Exchange and applicable only to trading on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange believes that waiver of the operative delay is appropriate because, as the Exchange discussed above, excluding Stop-Limit orders from the fat finger check, which would currently cancel/reject a Stop-Limit order if its buy (sell) limit price was above (below) the NBO (NBB) upon activation of its stop limit price, will benefit market participants by ensuring that they are able to use Stop-Limit orders to achieve their intended purpose. Thus, the Exchange believes that the proposed rule change is designed to protect investors by allowing their Stop-Limit orders to execute as intended without being canceled or rejected due to the application of the fat finger check provision.

The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal will permit Stop-Limit orders to execute as intended and not be inadvertently cancelled in certain situation, as discussed above, by the fat finger check provision. Therefore, the Commission hereby waives the

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *Id.*

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

operative delay and designates the proposal as operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2019–102 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–CBOE–2019–102. 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–CBOE–2019–102 and should be submitted on or before November 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24362 Filed 11–7–19; 8:45 am]

BILLING CODE 8011–01–P

[15] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87450; File No. SR–ICEEU–2019–023]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Revised Clearing Fees

November 4, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 28, 2019, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(2)[4] thereunder, so that the proposed rule change was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise clearing fees applicable to certain ICE Futures Europe Limited (''IFEU'') Financial Contracts. The revisions do not involve any changes to the ICE Clear Europe Clearing Rules or Procedures.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission or Advance Notice

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission or Advance Notice

(a) Purpose

The purpose of the proposed rule change is for ICE Clear Europe to modify certain clearing fees relating to certain IFEU Products as set out below:

- One Month Euro Overnight Rate Index Futures Contract (Block Only): The clearing fee will increase from GBP 0.20 to GBP 0.45 per lot.
- One Month Euro Overnight Rate Index Futures Contract (Block with Delayed Publication): The clearing fee will increase from GBP 0.34 to GBP 0.90 per lot.
- One Month Euro Overnight Rate Index Futures Contract (Cash Settlement): The clearing fee will increase from GBP 0.25 to GBP 0.56 per lot.
- One Month Euro Overnight Rate Index Futures Contract (Futures Contracts): The clearing fee will increase from GBP 0.20 to GBP 0.45 per lot.

(b) Statutory Basis

ICE Clear Europe has determined that the proposed fee changes set forth above are reasonable and appropriate. In particular, ICE Clear Europe believes that the fees have been set at an appropriate level given the costs and expenses to ICE Clear Europe in offering clearing of such IFEU Products, taking into account the investments ICE Clear Europe has made in clearing the markets for these products. The fees will apply to all F&O Clearing Members. ICE Clear Europe believes that imposing such charges thus provides for the equitable allocation of reasonable dues, fees, and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules.

other charges among its Clearing Members, within the meaning of Section 17A(b)(3)(D) of the Act. ICE Clear Europe therefore believes that the proposed rule change is consistent with the requirements of Section 17A of the Act and regulations thereunder applicable to it.

(B) Self-Regulatory Organization's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. Although the changes may result in certain additional costs to Clearing Members, ICE Clear Europe believes that the revised fees have been set at an appropriate level given the costs and expenses to ICE Clear Europe in offering clearing of the IFEU Products. ICE Clear Europe does not believe that the revised fees would adversely affect the ability of such Clearing Members or other market participants generally to engage in cleared transactions or to access clearing. Since the revised fees will apply to all F&O Clearing Members, ICE Clear Europe further believes that the fees will not otherwise adversely affect competition among Clearing Members, adversely affect the market for clearing services or limit market participants' choices for obtaining clearing services.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed changes to the rules have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change, Security-Based Swap Submission and Advance Notice and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A)[6] of the Act and Rule 19b–4(f)(2)[7] thereunder because it establishes a fee or other charge imposed by ICE Clear Europe on its Clearing Members. Specifically, the proposed rule changes will establish fees to be paid by Clearing Members to ICE Clear Europe in connection with the clearing of certain IFEU Products. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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–ICEEU–2019–023 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–ICEEU–2019–023. 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, security-based swap submission or advance notice that are filed with the Commission, and all written communications relating to the proposed rule change, security-based swap submission or advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.* 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–ICEEU–2019–023 and should be submitted on or before November 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24363 Filed 11–7–19; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(2).

[8] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 10927]

60-Day Notice of Proposed Information Collection: Employee Self-Certification and Ability To Perform in Emergencies (ESCAPE) Posts, Pre-Deployment Physical Exam Acknowledgement Form

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to January 7, 2020.

ADDRESSES:

You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2019–0036'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: Fieldke@state.gov.*
- *Regular Mail:* Send written comments to: Medical Director, Office of Medical Clearances, Bureau of Medical Services, 2401 E Street NW, SA–1, Room L–101, Washington, DC 20522–0101.
- *Fax:* 202–647–0292 Attention: Medical Clearance Director.

You must include the DS form number (if applicable), information

collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, should be sent to Karl Field, Director of Medical Clearances at 202–663–1591 or *Fieldke@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Employee Self-Certification and Ability to Perform in Emergencies (ESCAPE) Posts, Pre-Deployment Physical Exam Acknowledgement Form.
- *OMB Control Number:* 1405–0224.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Medical Services; MED/CP/CL.
- *Form Number:* DS–6570.
- *Respondents:* Contractors deploying to ESCAPE Diplomatic Missions requesting access to the Department of State Medical Program (currently Iraq, Afghanistan, Yemen, Syria, Libya, Somalia and Peshawar).
- *Estimated Number of Respondents:* 1,900.
- *Estimated Number of Responses:* 1,900.
- *Average Time per Response:* 40 minutes.
- *Total Estimated Burden Time:* 1,266 hours.
- *Frequency:* Annually for those deployed to an ESCAPE post.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The DS–6570 is completed by an individual and their medical provider to declare that the individual has health concerns that may represent a safety hazard for the individual or others at an ESCAPE Diplomatic Mission. ESCAPE is an acronym used to describe Diplomatic Missions overseas that are in extremely high threat, potentially combat, areas. Current ESCAPE Missions are Iraq, Afghanistan, Somalia, Libya, Yemen, Syria and Peshawar, Pakistan. This program is authorized under the Foreign Service Act of 1980, as implemented by the Department in 13 FAM 301.4–5.

Methodology

The respondent will obtain the DS–6570 from his or her human resources representative, or will download the form from a Department website. The respondent will complete and submit the form offline.

Karl Field,

Director of Medical Clearances.

[FR Doc. 2019–24390 Filed 11–7–19; 8:45 am]

BILLING CODE 4710–36–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 752]

Association of American Railroads—Petition for Rulemaking

AGENCY: Surface Transportation Board.

ACTION: Solicitation of information.

SUMMARY: The Surface Transportation Board (STB or Board) seeks information on whether and how particular cost-benefit analysis approaches might be more formally integrated into its rulemaking process.

DATES: Comments addressing the information requests described below will be due by January 17, 2020. Replies will be due by March 6, 2020.

ADDRESSES: Comments and replies may be filed with the Board either via e-filing or in writing addressed to: Surface Transportation Board, Attn: Docket No. EP 752, 395 E Street SW, Washington, DC 20423–0001. Comments and replies will be posted to the Board's website at *www.stb.gov.*

FOR FURTHER INFORMATION CONTACT: Sarah Fancher at (202) 245–0355. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On March 14, 2019, the Association of American Railroads (AAR) filed a petition to institute a rulemaking to adopt procedural rules that would require a cost-benefit analysis in certain Board rulemaking proceedings and would set certain data requirements. In response to the petition, the Board received filings from the Competitive Enterprise Institute, the Western Coal Traffic League, the Joint Shippers,[1] the National Grain and Feed Association, the American Forest & Paper Association, and the American Fuel & Petrochemical Manufacturers.

On July 10, 2019, the Board issued a decision waiving the provision at 49 CFR 1110.2(d), which requires the Board to rule on a petition for a rulemaking within 120 days of the filing of the petition. In that decision, the Board deferred action to allow the Board to further consider the issues raised in the petition.[2] The Board continues to consider the practices at other agencies, including other independent agencies that do not have cost-benefit analysis procedural rules,[3] and the Board now finds that it would be helpful to solicit additional information. To assist the Board's evaluation of whether and how particular cost-benefit analysis approaches might be more formally integrated into its rulemaking process, the Board seeks the following information:

1. *Methods.* The Board requests information on specific methods—not just general criteria and processes in best practices guides, which the Board has reviewed—that would assist in the qualitative or quantitative analysis of a final rule by the Board. Commenters may wish to draw upon academic literature, other economic regulatory agencies' analyses, or other sources to

[1] The Joint Shippers consist of the Agricultural Retailers Association, American Chemistry Council, American Malting Barley Association, Corn Refiners Association, Freight Rail Customer Alliance, Industrial Minerals Association—North America, Institute of Scrap Recycling Industries, Louisiana Chemical Association, National Association of Chemical Distributors, National Industrial Transportation League, Private Railcar Food and Beverage Association, The Chlorine Institute, The Fertilizer Institute, and the Vinyl Institute.

[2] AAR filed a petition for reconsideration of the Board's July 10 decision. Because the 120-day deadline waived in the Board's decision passed on July 12, 2019, the petition to reconsider the waiver is moot. Further, with respect to the additional Board action AAR requests in its reconsideration petition, that request is also moot because, in this decision, the Board is soliciting additional information as specified, *infra,* so that it can give further consideration to the AAR petition to institute a rulemaking, just as the Board indicated it would do in its July 10 decision. The Board expects the responses to this solicitation will be helpful to its consideration of the issues, and at this time, the Board is not denying or granting the AAR petition to institute a rulemaking.

[3] Neither the Board's authorizing legislation nor the Administrative Procedure Act requires the Board to conduct formal cost-benefit analysis. *See Village* of *Barrington, Ill.* v. *STB,* 636 F.3d 650, 670–71 (D.C. Cir. 2011); *see also BNSF Ry.* v. *STB,* 526 F.3d 770, 776 (D.C. Cir. 2008).

demonstrate how the Board might identify, and to the extent practicable quantify, specific benefits, costs, and transfer payments. The Board seeks specific methods directly applicable to regulatory issues within the Board's jurisdiction, including the economic regulation of freight railroads. To the extent that commenters reference studies, analyses, or other sources covering other types of regulation or industries, the Board requests that commenters describe in detail the application of the methods to the economic regulation of railroads. Such methods should account for the differences between rules that establish the processes under which administrative litigation takes place and other types of rules that prescribe a particular action or technology without such processes.

2. *Data.* The Board seeks suggestions regarding specific data that the Board collects or could collect to assist with cost-benefit analysis. Commenters may wish to describe potential uses of the Board's established data collections, such as the Waybill Sample or the reports submitted by Class I carriers, or potential changes to those collections, that would help facilitate or inform cost-benefit analysis. Commenters may also wish to describe new or additional data that the Board might start to collect and analyze, and suggest procedures for doing so, to assist in cost-benefit analysis.

3. *Application.* The Board seeks a detailed description of how cost-benefit analysis would apply to a hypothetical rulemaking, using the methods and data sources identified in response to items 1 and 2 above. Specifically, the Board suggests that commenters consider a hypothetical proposed rule to modify the revenue-variable cost (R/VC) percentage used for purposes of market dominance from 180% to 165%. For purposes of this hypothetical, commenters should assume the Board has the authority to modify 49 U.S.C. 10707(d)(1)(A) and should not address the statutory constraint in their comments.[4] To the extent practicable, the comments should provide a detailed example of how the Board would conduct a cost-benefit analysis of this hypothetical proposed rule utilizing appropriate methods and data sources.

4. *Threshold.* The Board requests information on the threshold for determining the rulemaking proceedings to which any cost-benefit analysis procedures should apply. Commenters may wish to identify qualitatively or quantitatively a category or categories of rules.

Again, the Board expects to take responses to this solicitation into consideration in connection with its decision on AAR's petition to institute a rulemaking, which the Board is not denying or granting at this time. The requested information will be helpful to the Board's continued consideration of the issues raised in AAR's petition to institute a rulemaking. This decision is consistent with AAR's suggestion that the Board move forward with a ''transparent process that allows for relevant input from all interested stakeholders'' and to ''open the issue for public comment.'' (Pet. for Recons. 2–3.)

Comments addressing the information requests described above will be due by January 17, 2020. Replies will be due by March 6, 2020.

Board decisions and notices are available at *www.stb.gov.*

It is ordered:

1. Comments as described above are due by January 17, 2020.

2. Replies are due by March 6, 2020.

3. AAR's petition for reconsideration of the July 10 decision is denied as moot.

4. This decision is effective on its date of service.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Decided: November 4, 2019.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–24436 Filed 11–7–19; 8:45 am]

BILLING CODE 4915–01–P

[4] By suggesting this hypothetical proposed rule, the Board does not intend to convey any view on the statutory R/VC percentage, which the Board lacks authority to modify. The hypothetical was selected to provide commenters a common example with which to apply their views and suggestions on methods and data sources.

SURFACE TRANSPORTATION BOARD

[Docket No. MCF 21088]

Transportation Demand Management Holdings, LLC—Acquisition of Control—Badger Bus Transportation Group, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving and authorizing finance transaction.

SUMMARY: On October 9, 2019, Transportation Demand Management Holdings, LLC (Holdings), a noncarrier, filed an application for Holdings to acquire control of Badger Bus Transportation Group, Inc. (Badger Group), a noncarrier that controls, among other entities, an interstate and intrastate motor carrier, Badger Coaches, Inc. (Badger Coaches), from Badger Group's shareholders, David H. Meier, John R. Meier, and James A. Meier, and the various family trusts they control (collectively, Sellers). The Board is tentatively approving and authorizing the transaction, and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules at 49 CFR 1182.5 and 1182.8.

DATES: Comments may be filed by December 23, 2019. If any comments are filed, Holdings may file a reply by January 7, 2020. If no opposing comments are filed by December 23, 2019, this notice shall be effective on December 24, 2019.

ADDRESSES: Comments may be filed with the Board either via e-filing or in writing addressed to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, send one copy of comments to: Andrew K. Light, Scopelitis, Garvin, Light, Hanson & Feary, P.C., 10 W Market Street, Suite 1400, Indianapolis, IN 46204.

FOR FURTHER INFORMATION CONTACT: Sarah Fancher at (202) 245–0355. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: According to the application, Holdings, which is organized under the laws of Texas, directly owns and controls Transportation Demand Management, LLC (TDM), which is organized under the laws of Washington. (Appl. 2.) TDM is a passenger motor carrier that holds interstate motor carrier authority, as well as intrastate motor carrier authority in Washington. (*Id.*) TDM conducts business as Starline Luxury Coaches, Wheatland Express, Starline Transportation, and A&A Motorcoach, and utilizes approximately 99 passenger-carrying vehicles and 119 drivers. (*Id.*)

The majority equity and voting membership interest in Holdings is owned and held by CVG Group, LLC (CVG), which is organized under the laws of Texas. (*Id.*) The membership interests of CVG are held evenly by Michael T. Gibson and Willard L. Jackson. (*Id.*) A noncontrolling equity membership interest in Holdings is directly and indirectly held by Gladys Gillis, the chief executive officer of Holdings. (*Id.*) Holdings states that TDM is the only interstate passenger motor carrier with which CVG, Holdings, Gibson, Jackson, and Gillis are affiliated. (*Id.* at 3.)

Holdings states that the purpose of the transaction is to acquire control of

Badger Group, a Wisconsin corporation that holds all equity interests in Badger Coaches,[1] which operates primarily as a motor carrier providing interstate charter services in Wisconsin and its surrounding areas, as well as intrastate passenger line run, shuttle, and charter services in Wisconsin. (*Id.* at 1, 3.) Badger Coaches holds interstate, and Wisconsin intrastate, passenger motor carrier authority. Badger Coaches utilizes approximately 71 passenger vehicles and 96 drivers.[2] (*Id. at 3.*)

Holdings represents that Sellers own all the issued and outstanding equity stock of Badger Group. (*Id.* at 5.) Holdings also states that Sellers do not have any direct or indirect ownership interest in any interstate passenger motor carrier other than Badger Coaches as described above. (*Id.*)

Holdings represents that, through this transaction, it will acquire all of the outstanding equity and voting stock of Badger Group, which will place Badger Coaches under Holdings' control. (*Id.*)

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public, (2) the total fixed charges that result, and (3) the interest of affected carrier employees. Holdings has submitted the information required by 49 CFR 1182.2, including information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), *see* 49 CFR 1182.2(a)(7), and a jurisdictional statement under 49 U.S.C. 14303(g) that the aggregate gross operating revenues of TDM and Badger Coaches exceeded $2 million during the 12-month period immediately preceding the filing of the application, *see* 49 CFR 1182.2(a)(5).

Holdings states that it does not expect the proposed transaction to have a material, detrimental impact on the adequacy of transportation services available to the public. (Appl. 6.) Holdings anticipates that services to the public will be improved as efficiencies are realized and capacity is added. (*Id.*) Holdings states that for the foreseeable future, Badger Coaches will continue to provide the same services it currently provides under the same name, but will operate as a subsidiary of Holdings, which is experienced in passenger transportation operations. (*Id.*) Holdings explains that Badger Coaches is experienced in some of the same market segments already served by Holdings' subsidiary, TDM. (*Id.* at 6–7.) Thus, the transaction is expected to result in operating efficiencies and cost savings derived from economies of scale and increased purchasing power, all of which will help ensure the provision of adequate service to the public. (*Id.* at 7.) Holdings also asserts that its acquisition of control of Badger Coaches will enhance the viability of Badger Coaches, Holdings, and TDM, which will in turn ensure the continued availability of adequate passenger transportation service for the public. (*Id.*)

Holdings claims that neither competition nor the public interest will be adversely affected by the proposed transaction. (*Id.* at 9.) Holdings explains that the market is competitive for motor coach passenger line-run, shuttle, and interstate charter services in Madison, Wis., and Southern Wisconsin (the Service Area). (*Id.*) Holdings states that Badger Coaches competes directly with other motor coach passenger line-run providers in the Service Area, including Megabus, Greyhound, Lamers Bus Lines, and Jefferson Lines. (*Id.*) Holdings notes that Lamers Bus Lines and Jefferson Lines, among others, also provide shuttle and charter services in the Service Area. (*Id.*) Holdings states that passenger transportation arrangers for charter and tour services, as well as rail transportation, air transportation, and automobiles, provide further competition in the Service Area. (*Id.*) Holdings affirms that the services offered by Badger Coaches are geographically ''dispersed'' from those offered by TDM, and there is no overlap in the service areas and customer bases between Badger Coaches and TDM. (*Id.*) TDM operates in Washington and elsewhere, and Badger Coaches operates in Wisconsin and its surrounding area. (*Id.* at 2–3.)

Holdings states that the proposed transaction will increase fixed charges in the form of interest expenses because funds will be borrowed to assist in financing the transaction; however, Holdings maintains that the increase will not impact the provision of transportation services to the public. (*Id.* at 7.) Holdings also asserts that it does not expect the transaction to have substantial impacts on employees or labor conditions, and it does not anticipate a measurable reduction in force or changes in compensation levels or benefits at Badger Coaches. (*Id.* at 7–8.) Holdings submits, however, that staffing redundancies could result in limited downsizing of back-office or managerial-level personnel. (*Id.* at 8.)

The Board finds that the acquisition as proposed in the application is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6. If no opposing comments are filed by expiration of the comment period, this notice will take effect automatically and will be the final Board action.

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available at *www.stb.gov.*

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective December 24, 2019, unless opposing comments are filed by December 23, 2019.

4. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW, Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE, Washington, DC 20590.

Decided: October 31, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2019–24419 Filed 11–7–19; 8:45 am]

BILLING CODE 4915–01–P

[1] Additional information about Badger Coaches (also referred to in the application as Badger Coach) and TDM, including U.S. Department of Transportation (USDOT) numbers, motor carrier numbers, and USDOT safety fitness ratings, can be found in the application. (*See* Appl. 2–4.)

[2] Holdings states that Badger Group also holds all of the equity interests in Wisconsin intrastate passenger carriers Badger Bus Lines, Inc., and Meier Truck Services, LLC, and in noncarriers Badger Tour & Travel, LLC, and Meier Coach Leasing. (*Id.* at 3–4.)

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36347]

Bessemer and Lake Erie Railroad Company—Acquisition and Operation—Certain Rail Lines of CSX Transportation, Inc. in Onondaga, Oswego, Jefferson, Saint Lawrence, and Franklin Counties, NY

AGENCY: Surface Transportation Board.

ACTION: Decision No. 1 in Docket No. FD 36347; notice of acceptance of application; issuance of Procedural Schedule.

SUMMARY: The Surface Transportation Board (Board) is accepting for consideration the application filed on October 11, 2019, by Bessemer and Lake Erie Railroad Company (B&LE or Applicant).[1] The application seeks Board approval for B&LE, an indirect wholly owned rail carrier subsidiary of Canadian National Railway Company (CNR), to acquire from CSX Transportation, Inc. (CSXT), and to operate approximately 236.3 miles of rail line in New York. This proposal is referred to as the Transaction.

The Board finds that the application is complete and that the Transaction is a minor transaction based upon the preliminary determination that the Transaction clearly would not have any anticompetitive effects and that, if any such anticompetitive effects were found to exist, they would clearly be outweighed by the Transaction's anticipated contribution to the public interest in meeting significant transportation needs. The Board makes this preliminary determination based on the evidence presented in the application. The Board emphasizes that this is not a final determination and may be rebutted by subsequent filings and evidence submitted into the record for this proceeding. The Board will carefully consider any claims that the Transaction would have anticompetitive effects.

DATES: The effective date of this decision is November 8, 2019. Any person who wishes to participate in this proceeding as a Party of Record must file, no later than November 25, 2019, a notice of intent to participate. All comments, protests, requests for conditions, and any other evidence and argument in opposition to the primary application and related filings, including filings by the U.S. Department of Justice (DOJ) and the U.S. Department of Transportation (DOT), must be filed by December 9, 2019. Responses to comments, protests, requests for conditions, other opposition, and rebuttal in support of the primary application or related filings must be filed by January 8, 2020. *See* Procedural Schedule. A final decision in this matter will be served no later than February 21, 2020. Further procedural orders, if any, would be issued by the Board, if necessary.

ADDRESSES: Any filing submitted in this proceeding must be filed with the Board either via e-filing or in writing addressed to: Surface Transportation Board, 395 E Street, SW, Washington, DC 20423–0001. In addition, one copy of each filing must be sent (and may be sent by email only if service by email is acceptable to the recipient) to each of the following: (1) Secretary of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) Attorney General of the United States, c/o Assistant Attorney General, Antitrust Division, Room 3109, Department of Justice, Washington, DC 20530; (3) Applicant's representative, Claire M. Maddox, Dentons US LLP, 1900 K Street NW, Washington, DC 20006; and (4) any other person designated as a Party of Record on the service list notice. As explained below, the service list notice will be issued as soon after November 25, 2019, as practicable.

FOR FURTHER INFORMATION CONTACT: Amy Ziehm at (202) 245–0391. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Applicant is an indirect wholly owned rail carrier subsidiary of CNR that owns and operates approximately 159 miles of railroad lines in Ohio and Pennsylvania. (Appl. 1, 19.) CSXT is a Class I railroad that owns and operates approximately 21,000 miles of railroad lines. (*Id.* at 19.) Applicant seeks the Board's prior review and authorization pursuant to 49 U.S.C. 11323–25 to acquire and operate certain CSXT lines, collectively known as the Massena Lines, from Woodard, NY, to the U.S.-Canadian border near Fort Covington, NY. (Appl. 1–2.) More specifically, these lines consist of CSXT's St. Lawrence Subdivision between CSXT milepost QM 3.0 at or near Woodard and CSXT milepost QM 183.1 at or near Fort Covington, on the U.S.-Canadian border, a distance of approximately 179.2 miles; CSXT's Fulton Subdivision between CSXT milepost QMF 7.2 at or near a connection to CSXT's St. Lawrence Subdivision near Woodard and CSXT milepost QMF 37.95 at or near Fort Ontario, NY, a distance of approximately 31 miles; CSXT's Balmat Industrial Track between CSXT milepost QMB 0 at or near a connection with CSXT's St. Lawrence Subdivision near CSXT milepost QM 107 and CSXT milepost QMB 9, a distance of approximately 9 miles; CSXT's Rooseveltown Industrial Track between CSXT milepost QMR 63 at or near a connection with the St. Lawrence Subdivision at Helena, NY, and CSXT milepost QMR 68 at or near Rooseveltown, NY, a distance of approximately 5 miles; and CSXT's Carthage Branch between CSXT milepost QMC 86.8 at or near a connection with CSXT's St. Lawrence Subdivision near Philadelphia, NY, and CSXT milepost QMC 74.7 at or near Regis, NY, a distance of approximately 12 miles and CSXT's connection with Mohawk, Adirondack, and Northern Railroad Corporation. (*Id.* at 21–22.) The Transaction is part of a larger purchase agreement, under which CNR and B&LE have agreed to acquire from CSXT approximately 278.1 miles of rail line (including the 236.3 miles that comprise the Massena Lines) between Beauharnois, Que., and Woodard, pursuant to a Purchase and Sale Agreement (PSA)[2] that was executed on August 29, 2019.[3] (*Id.* at 1–2, 7 & Ex. 2, Purchase & Sale Agreement.)

Applicant states that more than 45% of current carload traffic on the Massena Lines is overhead traffic exchanged between the CN System[4] and CSXT, for which the Massena Lines provide a direct connection and gateway. (*Id.* at 9.) By acquiring the Massena Lines, Applicant seeks to preserve the CN System's direct connection with CSXT for overhead traffic that currently moves over the Massena Lines and to ensure that traffic using the Massena Lines would continue to move directly between the two systems, rather than through an additional railroad. (*Id.*) Applicant also seeks to improve efficiencies of operations along the Massena Lines and work with customers on the Massena Lines to understand their rail service needs, develop efficient plans for rail operations to their facilities, and help them grow their future businesses. (*Id.* at 10.)

Financial Arrangements. According to Applicant, no new securities would be issued in connection with the Transaction. Applicant states that the only relevant financial arrangement is the payment of the purchase price by CNR and B&LE, as provided in the PSA. (*Id.* at 11.)

[1] Applicant initially submitted its application on October 10, 2019. On October 11, 2019, Applicant amended its original submission to correct a signature page that was inadvertently left blank. Accordingly, October 11, 2019 will be considered the filing date of the application for the purposes of this proceeding.

[2] Applicant submitted a copy of the PSA with its application and designated the PSA as ''highly confidential,'' thus subject to the provisions of the protective order issued by the Board on October 22, 2019.

[3] Applicant identifies CSX Intermodal Terminals, Inc., and St. Lawrence and Adirondack Railway Company, together with CSXT, as ''CSX Parties'' to the PSA. (Appl. 7.)

[4] Applicant defines ''CN System'' as the rail system operated in Canada by CNR and in the United States by CN, which it defines as CNR's U.S. rail operating subsidies, including B&LE. (Appl. iv.)

Passenger Service Impacts. Applicant states that the Transaction would have no impact on commuter or other passenger rail service, because no such services are provided on the Massena Lines, nor have there been any such services on the lines since at least the establishment of the National Railroad Passenger Corporation (Amtrak) in 1971. (*Id.,* Ex. 15 at 10.)

Discontinuances/Abandonments. Applicant states that it does not plan to abandon or discontinue service on rail lines in the United States as a result of the Transaction. (*Id.,* Ex. 15 at 10.) As discussed below, Applicant states that, before closing, it plans to seek formal discontinuance of its inactive 1989 trackage rights on CSXT's St. Lawrence Subdivision between Fort Covington and Massena, NY, under the Board's class exemption procedures at 49 CFR 1152.50 for trackage rights that have not been utilized within the past two years. (*Id.* at 10–11.)

Public Interest Considerations. Applicant asserts that the Transaction would not result in the lessening of rail competition, creation of a monopoly, or restraint of trade in freight surface transportation in any region of the United States. (Appl. at 12.) Applicant states that the transaction is an end-to-end line acquisition, with a ''principal effect'' being the relocation of an interchange point between the CN System and CSXT from Huntingdon, Que., to Woodard, extending the length of the CN System's haul and shifting operations on the Massena Lines from CSXT to B&LE. (*Id.*) Applicant notes that the Transaction would not render other trackage duplicative or redundant and that the CN System and CSXT have no network overlap in the United States in the vicinity of the Massena Lines. (*Id.*)

Applicant asserts that the Transaction would maintain the competitive status quo. According to the Applicant, customers on the Massena Line currently receive direct service from a single carrier, CSXT, and they would not see a reduction in the number of competitive rail options available by substituting direct B&LE service for direct CSXT service. (*Id.* at 12.) Applicant states that, in 1989, CNR retained trackage rights over the main line between Fort Covington and Massena in connection with the purchase by Consolidated Rail Corporation (Conrail) of what was previously CNR's line between Massena and Huntingdon. (*Id.* at 12–13.) As part of that line sale, CNR retained certain limited trackage rights to exclusively serve ''present industries [as of 1989] and their successors''; Conrail obtained the exclusive right (held by CSXT since 1999) to serve new industries. Thus, no individual industry on that line segment has ever been served by more than one carrier. (*Id.*) The 1989 trackage rights also permitted CNR to interchange with the Massena Terminal Railroad Company (MSTR) at Massena. (*Id.* at 13.) However, Applicant asserts that CNR has neither operated to Massena nor conducted any interchange with MSTR for at least 14 years and that the substitution of B&LE for CSXT as the owner of the Massena Lines would effectuate no meaningful change in the interchange and handling of traffic with MSTR at Massena. (*Id.* at 14 & V.S. Drysdale 7–8.) As noted above, Applicant states that, before closing, CNR plans to seek formal discontinuance of its inactive 1989 trackage rights under the Board's class exemption procedures at 49 CFR 1152.50. (*Id.* at 13–14.)

Moreover, Applicant asserts that the Transaction would cause no reduction in the number of transloading or intermodal service options. (*Id.* at 14.) Applicant states that, by maintaining the existing CN System-CSXT gateway over the Massena Lines, without the need for an added interchange with a third rail carrier, the Transaction would preserve existing levels of competition for rail transportation to and from the northeastern United States. (*Id.* at 15.)

Applicant further states that, following B&LE's acquisition of the Massena Lines, it would have opportunities to improve the efficiencies of operations along the Massena Lines, such as eliminating two CSXT transfer assignments now operating between Massena and Huntingdon. (*Id.* at 10.) Applicant contends that elimination of these two transfer assignments would avoid delays and improve overall efficiency of operations by reducing estimated total transit time by approximately 24 hours. (*Id.*)

Time Schedule for Consummation. Applicant states that the Transaction is scheduled to be consummated immediately upon satisfaction of all conditions precedent set forth in the PSA, including Board approval of B&LE's application and the Board's approval decision becoming effective. (*Id.* at 8.)

Environmental Impacts. Applicant states that, pursuant to 49 CFR 1105.6(c)(1), the Transaction is exempt from environmental reporting requirements because the environmental impacts of the Transaction fall below the thresholds established in 49 CFR 1105.7(e)(4) and (5). (*Id.* at 23–25.)

Historic Preservation Impacts. Applicant states that no historical reporting is required under 49 CFR 1105.8, as rail operations would continue after Applicant's purchase of the Massena Lines, and Applicant has no plans to dispose of or alter properties subject to the Board's jurisdiction that are 50 years old or older. (*Id.* at 25.)

Labor Impacts. Applicant states that CSXT currently employs 50 employees on the Massena Lines who may be adversely affected by the Transaction. (*Id.* at 17.) Applicant states that no current CN employees in the United States would be adversely affected by the Transaction. (*Id.*) B&LE states that it does not have employees in New York and would therefore be hiring an estimated 53 employees to operate the Massena Lines. (*Id.,* Ex. 15 at 11.) B&LE plans to offer priority hiring consideration to CSXT employees working on the Massena Lines in New York. (*Id.* at 17 & Ex. 15 at 11.)

Applicant states that any employees adversely impacted by the Transaction would be entitled to labor protective conditions in accordance with *New York Dock Railway—Control—Brooklyn Eastern District Terminal,* 360 I.C.C 60, *aff'd New York Dock Railway* v. *United States,* 609 F.2d 83 (2d Cir. 1979), as modified by *Wilmington Terminal Railroad—Purchase & Lease—CSX Transportation Inc.,* 6 I.C.C. 2d 799, 814–26 (1990), *aff'd sub nom. Railway Labor Executives' Ass'n* v. *ICC,* 930 F.2d 511 (6th Cir. 1991).

Primary Application and Related Filings Accepted. The Board finds that the proposed Transaction would be a ''minor transaction'' under 49 CFR 1180.2(c), and the Board accepts the application for consideration because it is in substantial compliance with the applicable regulations governing minor transactions. *See* 49 U.S.C. 11321–26; 49 CFR pt. 1180. The Board reserves the right to require the filing of supplemental information as necessary to complete the record.

When a transaction does not involve the merger or control of two or more Class I railroads, the Board's treatment differs depending upon whether the transaction would have ''regional or national transportation significance.'' 49 U.S.C. 11325. Under 49 CFR 1180.2, a transaction that does not involve two or more Class I railroads is to be classified as ''minor''—and thus not having regional or national transportation significance—if a determination can be made that either: (1) The transaction clearly will not have any anticompetitive effects; or (2) any anticompetitive effects will clearly be outweighed by the transaction's

anticipated contribution to the public interest in meeting significant transportation needs. A transaction not involving the control or merger of two or more Class I railroads is to be classified as ''significant'' if neither of these determinations can be made.

Nothing in the record thus far suggests that the Transaction would have anticompetitive effects. The Transaction is an end-to-end acquisition involving approximately 236.3 miles of rail line in the state of New York. As Applicant notes, the Board has held that end-to-end transactions are unlikely to raise competitive concerns. *See Norfolk S. Ry.—Joint Control & Operating/ Pooling Agreements—Pan Am S. LLC,* FD 35147 et al., slip op. at 5 (STB served Mar. 10, 2009). The application indicates that the Transaction would maintain the competitive status quo, as local customers located on the Massena Lines are exclusively served by CSXT now and would be exclusively served by B&LE following the Transaction. Additionally, it appears that the Transaction would not cause a reduction in the number of transloading or intermodal service options.

Moreover, if anticompetitive effects resulting from the Transaction should later be shown to be likely, they would appear, from the face of the application, to be clearly outweighed by the Transaction's contribution to the public interest in meeting significant transportation needs. As noted in the application, CSXT announced in June 2018 that it was rationalizing its system by selling several lines, including the Massena Lines, that CSXT identified as not being core to its business and that could be more valuable to other operators well positioned to further improve the lines and better serve local customers. (*See* Appl. 8–9.) With B&LE acquiring the Massena Lines, the Transaction would ensure that overhead traffic currently moving over the Massena Lines between the CN System and CSXT would continue to move directly between the two systems on that route, rather than via a third, bridge carrier on that route or via a different direct CN System-CSXT gateway that likely would be longer and less efficient than the current route.

Therefore, based on the information provided in the application, the Board finds the proposed Transaction to be a minor transaction under 49 CFR 1180.2(c). Such a categorization does not mean that the proposed Transaction is insignificant or not of importance. Indeed, after the record in the proceeding is fully developed, the Board will carefully review the proposed Transaction to make certain that it does not substantially lessen competition, create a monopoly, or restrain trade and that any anticompetitive effects are outweighed by the public interest. *See* 49 U.S.C. 11324(d)(1)–(2). The Board may also impose conditions to mitigate or eliminate any anticompetitive impacts of the transaction.

Procedural Schedule. The Board has considered Applicant's motion for a procedural schedule, filed October 10, 2019. Applicant's proposed procedural schedule provides 30 days for comments from all parties on the application and 32 days for the concurrent filing of replies to comments and rebuttal in support of the application. The proposed procedural schedule then provides 85 days after the close of the evidentiary period for the Board to issue its final decision. The Board will adopt a procedural schedule that will allow 31 days for comments on the application and 30 days for replies to comments and rebuttal in support of the application. The Board is required to issue ''a final decision by the 45th day after the date on which it concludes the evidentiary proceedings,'' 49 U.S.C. 11325(d)(2), and will do so here.[5]

For further information regarding procedural dates, see the Procedural Schedule to this decision.

Notice of Intent to Participate. Any person who wishes to participate in this proceeding as a Party of Record must file with the Board, no later than November 25, 2019, a notice of intent to participate, accompanied by a certificate of service indicating that the notice has been properly served on the Secretary of Transportation, the Attorney General of the United States, and Applicant's representative.

If a request is made in the notice of intent to participate to have more than one name added to the service list as a Party of Record representing a particular entity, the extra name(s) will be added to the service list as a ''Non-Party.'' Any person designated as a Non-Party will receive copies of Board decisions, orders, and notices but not copies of official filings. Persons seeking to change their status must accompany that request with a written certification that he or she has complied with the service requirements set forth at 49 CFR 1180.4 and any other requirements set forth in this decision.

Service List Notice. The Board will serve, as soon after November 25, 2019, as practicable, a notice containing the official service list (the service list notice). Each Party of Record will be required to serve upon all other Parties of Record, within 10 days of the service date of the service list notice, copies of all filings previously submitted by that party (to the extent such filings have not previously been served upon such other parties). Each Party of Record will also be required to file with the Board, within 10 days of the service date of the service list notice, a certificate of service indicating that the service required by the preceding sentence has been accomplished. Every filing made by a Party of Record after the service date of the service list notice must have its own certificate of service indicating that all Parties of Record on the service list have been served with a copy of the filing. Members of the United States Congress and Governors are not Parties of Record and need not be served with copies of filings, unless any Member or Governor has requested to be, and is designated as, a Party of Record.

Service of Decisions, Orders, and Notices. The Board will serve copies of its decisions, orders, and notices on those persons who are designated on the official service list as a Party of Record or Non-Party. All other interested persons are encouraged to secure copies of decisions, orders, and notices via the Board's website at *www.stb.gov.*

Access to Filings. Under the Board's rules, any document filed with the Board (including applications, pleadings, etc.) shall be promptly furnished to interested persons on request, unless subject to a protective order. 49 CFR 1180.4(a)(3). The application and other filings in this proceeding will be furnished to interested persons upon request and will also be available on the Board's website at *www.stb.gov.*[6] In addition, the application may be obtained from Applicant's representative at the address indicated above.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

[5] This notice will be published in the **Federal Register** on November 8, 2019; all subsequent deadlines will be calculated from this date. Deadlines for filings are calculated in accordance with 49 CFR 1104.7(a).

[6] Applicant has submitted a public version and highly confidential version of its application. The public version is available on the Board's website. The highly confidential version may be obtained subject to the provisions of the protective order issued by the Board on October 22, 2019.

PROCEDURAL SCHEDULE

October 10, 2019	Motion for Protective Order and Motion for Establishment of Procedural Schedule filed.
October 11, 2019	Application (amended) filed.
November 8, 2019	Board notice of acceptance of application served and published in the **Federal Register**.
November 25, 2019	Notices of intent to participate in this proceeding due.
December 9, 2019	All comments, protests, requests for conditions, and any other evidence and argument in opposition to the application, including filings of DOJ and DOT, due.
January 8, 2020	Responses to comments, protests, requests for conditions, and other opposition due. Rebuttal in support of the application due.
February 21, 2020	Date by which a final decision will be served.
March 22, 2020.[7]	Date by which a final decision will become effective.

It is ordered:

1. The application is accepted for consideration.

2. The parties to this proceeding must comply with the procedural schedule adopted by the Board in this proceeding as shown in this decision. The parties to this proceeding must comply with the procedural requirements described in this decision.

3. This decision is effective on November 8, 2019.

Decided: November 4, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2019–24438 Filed 11–7–19; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Release of Land Affecting Federal Grant Assurance Obligations at Tucson International Airport, Tucson, Pima County, Arizona

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of request to release airport land.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment for the release of approximately 297 acres of airport land, otherwise known as Parcel H, at Tucson International Airport (TUS), Tucson, Pima County, Arizona from the aeronautical use provisions of the Grant Agreement Assurances since the land is not needed for airport purposes. The land for proposed release consists of two parcels along the southern boundary of the abandoned Hughes Access Road, adjacent to the main airport airfield sand campus, and a portion of property which is used by Aerospace Parkway. The land will be sold to the City of Tucson, to accommodate future expansion of a public roadway, and to permit future compatible development adjacent to United States Air Force Plant 44. The airport will be compensated for the fair market value of the land. The use of the land for a roadway and industrial development represents a compatible land use that will not interfere with the airport or its operation, thereby protecting the interests of civil aviation.

DATES: Comments must be received on or before December 9, 2019.

FOR FURTHER INFORMATION CONTACT: Comments on the request may be mailed or delivered to the FAA at the following address: Mr. Mike N. Williams, Manager, Phoenix Airports District Office, **Federal Register** Comment, Federal Aviation Administration, Phoenix Airports District Office, 3800 N. Central Avenue, Suite 1025, Phoenix, Arizona 85012. In addition, one copy of the comment submitted to the FAA must be mailed or delivered to Ms. Danette Bewley, Interim President/CEO, Tucson Airport Authority, 7200 S. Tucson Boulevard, Suite 300, Tucson, Arizona 85756.

SUPPLEMENTARY INFORMATION: In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 10–181 (Apr. 5, 2000; 114 Stat. 61), this notice must be published in the **Federal Register** 30 days before the DOT Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

The following is a brief overview of the request:

The Tucson Airport Authority (TAA) requested a release from the provisions of the Grant Agreement Assurances to permit the disposal of approximately 297 acres of land, otherwise known as Parcel H, at Tucson International Airport, Tucson, Pima County, Arizona to permit the expansion of a public road (Aerospace Parkway), and to permit future compatible development adjacent to United States Air Force Plant 44. The Tucson Airport Authority will sell the land, obligated by Airport Improvement Program grants, and Passenger Facility Charge funding. In return, TAA will be compensated for the fair market value for the property. An Environmental Impact Statement was completed for Parcel H, and a Record of Decision executed on November 28, 2018. The proposed use of the land is a compatible land use that will not interfere with or impede the operations and development of the airport. Based on the benefits of fair compensation and enhanced public safety, the interests of civil aviation will be properly served.

Issued in El Segundo, California, on November 4, 2019.

Original signed by

Brian Q. Armstrong,

Manager, Safety and Standards Branch, Airports Division, Western-Pacific Region.

[FR Doc. 2019–24452 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Charleston County, South Carolina; Notice of Intent

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The FHWA is issuing this notice of intent to advise the public that an Environmental Impact Statement will be prepared for a proposed highway project in Charleston County, South Carolina.

FOR FURTHER INFORMATION CONTACT: Emily O. Lawton, Division Administrator, Federal Highway Administration, Strom Thurmond Federal Building, 1835 Assembly Street, Suite 1270, Columbia, South Carolina 29201, Telephone: (803) 765–5411, Email: *emily.lawton@dot.gov.*

SUPPLEMENTARY INFORMATION: The Federal Highway Administration (FHWA), in cooperation with the South

[7] The final decision will become effective 30 days after it is served.

Carolina Department of Transportation (SCDOT), will be preparing an Environmental Impact Statement (EIS) for the I–526 West Lowcountry Corridor Improvements Project. The proposed project would make improvements to the I–526 corridor from Virginia Avenue to Paul Cantrell Boulevard in Charleston County, South Carolina. The purpose of the proposed project is to increase capacity and improve operations at the I–26/526 interchange and along the I–526 mainline from Virginia Avenue to Paul Cantrell Boulevard. The FHWA intends to issue a single Final EIS and Record of Decision (ROD) document pursuant to the FAST Act Section 1311 requirements, unless FHWA determines statutory criteria or practicability considerations preclude issuance of a combined document.

The I–526 and I–26 System-to-System interchange is a vital local connection, linking downtown Charleston, Summerville, West Ashley, and Mount Pleasant. I–26 links the Charleston area with the other major cities to the west like Columbia, Spartanburg, and Asheville, North Carolina, as well as with I–95, I–77, I–20, I–85, I–40, and I–81. In addition, I–526 provides the only freeway access to two important port terminals, the North Charleston terminal, and the Wando Welch terminal. Thus, I–526 is an important part of a network for transporting freight and commercial goods to and from the Port of Charleston and throughout the region.

The Charleston region's population growth is three times the average of the United States. With the increased population growth, traffic congestion is anticipated to worsen over the next 20 years. SCDOT has currently ranked I–526 between I–26 and Virginia Avenue as the most congested interstate segment in South Carolina. In addition, I–526 between I–26 and Paul Cantrell Boulevard is currently ranked among the top ten of South Carolina's most congested interstate corridors. Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand and to address the existing and projected future congestion.

Alternatives under consideration will evaluate mainline widening options along with several interchange improvements at I–26/I–526, North Rhett Avenue, and Rivers Avenue in addition to the no-build alternative. The alternatives will be refined during the NEPA scoping process in consideration of agency and public comments received.

The FHWA and SCDOT are seeking input as part of the scoping process to assist in identifying issues relative to this project and potential solutions. Letters describing the proposed action and soliciting comments are being sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed an interest in this project. Agency coordination will involve monthly meetings and a public information meeting will be held on November 21, 2019 from 11:00 a.m. to 7:00 p.m. at the North Charleston Convention Center that will allow the public to comment on the scope of the EIS, the purpose and need, the alternatives under evaluation, environmental impacts to be considered, and potential mitigation measures.

Further agency and community meetings will be held as the project is developed, and a public hearing will be conducted after the approval of the draft EIS. Public notice will be given of the time and place of the meetings and hearing. Meeting dates and locations will be posted on the project's website at *https://www.526lowcountrycorridor.com/west/* and all known interested parties and the public will be notified via postcards.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above no later than January 4, 2020.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Dated: November 1, 2019.

Yolonda Jordan,

Assistant Division Administrator, Columbia, South Carolina.

[FR Doc. 2019–24327 Filed 11–7–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Fiscal Service Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before December 9, 2019 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Spencer W. Clark by emailing *PRA@treasury.gov,* calling (202) 927–5331, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Bureau of the Fiscal Service (BFS)

Title: Pools and Associations—Annual Letter.

OMB Control Number: 1530–0007.

Type of Review: Reinstatement of a previously approved collection.

Description: Information collected determines acceptable percent for each pool and association Treasury Certified companies are given credit for on Treasury Schedule F for authorized ceded reinsurance in determining the companies' underwriting limitations.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 84.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 84.

Estimated Time per Response: 1.5 hours.

Estimated Total Annual Burden Hours: 126.

Title: FS Form 2888—Application Form for U.S. Department of Treasury Accountable Official Stored Value Card (SVC).

OMB Control Number: 1530–0020.

Type of Review: Extension without change of a currently approved collection.

Description: This form is used to collect information from accountable officials requesting enrollment in the Treasury SVC program in their official capacity, to obtain authorization to initiate debit and credit entries to their bank or credit union accounts to load value on the cards, and to facilitate collection of any delinquent amounts that may become due and owning as a result of the use of the cards.

Form: FS Form 2888.

Affected Public: Individuals and households.

Estimated Number of Respondents: 7,500.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 7,500.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 1,250.

Title: Request To Reissue United States Savings Bonds.

OMB Control Number: 1530–0025.

Type of Review: Revision of a currently approved collection.

Description: The information is requested to support a request to reissue paper (definitive) Series EE, HH, and I United States Savings Bonds, Retirement Plan Bonds, and Individual Retirement Bonds and to indicate the new registration required.

Form: FS Form 4000.

Affected Public: Individuals and households.

Estimated Number of Respondents: 38,000.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 38,000.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 19,000.

Title: Certificate of Identity.

OMB Control Number: 1530–0026.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to establish the identity of the owner of U.S. Savings Securities in a claim for payment by a disinterested person.

Form: FS Form 0385.

Affected Public: Individuals and households.

Estimated Number of Respondents: 1,400.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 1,400.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 234.

Title: Special Form of Request for Payment of U.S. Savings and Retirement Sec. Where Use of a Detached Request is authorized.

OMB Control Number: 1530–0028.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to establish ownership and request for payment of United States Savings Bonds, Savings Notes, Retirement Plan Bonds, and Individual Retirement Bonds.

Form: FS Form 1522.

Affected Public: Individuals and households.

Estimated Number of Respondents: 14,000.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 14,000.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 3,500.

Title: Claim for lost, stolen or destroyed United States registered Securities.

OMB Control Number: 1530–0029.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Registered Securities.

Form: FS Form 1025.

Affected Public: Individuals and households.

Estimated Number of Respondents: 10.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Title: Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Individuals).

OMB Control Number: 1530–0033.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Bearer Securities owned by individuals.

Form: FS Form 1022–1.

Affected Public: Individuals and households.

Estimated Number of Respondents: 10.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Title: Report/Application for Relief on Account of Loss, Theft or Destruction of U.S. Bearer Securities (Organizations).

OMB Control Number: 1530–0034.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Bearer Securities.

Form: FS Form 1022.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 10.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Title: Description of United States Savings Bonds Series HH/H and Description of United States Bonds/Notes.

OMB Control Number: 1530–0037.

Type of Review: Reinstatement of a previously approved collection.

Description: The information collected is necessary to obtain information describing an owner's holding of United States Securities.

Forms: FS Form 2490, FS Form 1980.

Affected Public: Individuals and households.

Estimated Number of Respondents: 950.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 950.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 95.

Title: Affidavit of Forgery for United States Savings Bonds.

OMB Control Number: 1530–0040.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to establish whether the registered owner signed the request for payment or if the signature was a forgery.

Form: FS Form 0974.

Affected Public: Individuals and households.

Estimated Number of Respondents: 10.

Frequency of Response: On occasion.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 3.

Title: Affidavit by Individual Surety.

OMB Control Number: 1530–0047.

Type of Review: Reinstatement of a previously approved collection.

Description: The information is requested to support a request to serve as surety for an indemnification agreement on a Bond of Indemnity.

Form: FS Form 4094.

Affected Public: Individuals and households.

Estimated Number of Respondents: 10.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 5, 2019.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2019–24444 Filed 11–7–19; 8:45 am]

BILLING CODE 4810–AS–P

FEDERAL REGISTER

Vol. 84 Friday,
No. 217 November 8, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, 484, et al.
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; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, 484, and 486

[CMS–1711–FC]

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: Final rule with comment period.

SUMMARY: This final rule with comment period updates the home health prospective payment system (HH PPS) payment rates and wage index for CY 2020; implements the Patient-Driven Groupings Model (PDGM), a revised case-mix adjustment methodology, for home health services beginning on or after January 1, 2020. This final rule with comment period 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 finalizes a 30-day payment amount for CY 2020. Additionally, this final rule with comment period: Modifies the payment regulations pertaining to the content of the home health plan of care; allows therapist assistants to furnish maintenance therapy; and changes the split percentage payment approach under the HH PPS. For the Home Health Value-Based Purchasing (HHVBP) model, we are finalizing provisions requiring the public reporting of 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. This final rule with comment period also finalizes the following updates to the Home Health Quality Reporting Program (HH QRP): Removal of a measure; adoption of two new measures; modification of an existing measure; and a requirement for HHA's to report standardized patient assessment data beginning with the CY 2022 HH QRP. Additionally, we are finalizing our proposal to re-designate our current HH QRP regulations in a different section of our regulations and to codify other current policies in that new regulatory section with one substantive change as well as a few technical edits. We are not finalizing our proposal to remove question 10 from all of the HH Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. Lastly, it sets forth routine updates to the home infusion therapy payment rates for CY 2020, payment provisions for home infusion therapy services for CY 2021 and subsequent years, and solicits comments on options to enhance future efforts to improve policies related to coverage of eligible drugs for home infusion therapy.

DATES: *Effective Date:* This final rule with comment period is effective January 1, 2020.

Comment Date: To be assured consideration, comments on the criteria that can be considered to allow coverage of additional drugs under the DME benefit discussed in section VI.D. of this final rule with comment period must be received at one of the addresses provided below, no later than 5 p.m. on December 30, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1711–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1711–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1711–FC, 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: Hillary Loeffler, (410) 786–0456, 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 final rule with comment period updates 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 rule also updates 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 final rule with comment period implements the PDGM, a revised case-mix adjustment methodology that was finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), which also implements 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 final rule with comment period allows therapist assistants to furnish maintenance therapy; finalizes changes to the payment regulations pertaining to the content of the home health plan of care; updates technical regulations text changes which clarifies the split-percentage payment approach for newly-enrolled HHAs in CY 2020 and changes the split percentage payment approach for existing HHAs in CY 2020 and subsequent years.

2. HHVBP

This final rule with comment period finalizes public reporting of 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 HHA that qualifies for a payment adjustment under the HHVBP Model for CY 2020.

3. HH QRP

This final rule with comment period finalizes 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 final rule with comment period finalizes payment provisions for home infusion therapy services for CY 2021 and subsequent years in accordance with section 1834(u) 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 final rule with comment period sets forth the 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 final rule with comment period 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 1895(b)(3) of the Act requires that we calculate this 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. The CY 2020 30-day payment amount (for those HHAs that report the required quality data) will be $1,864.03, which reflects an adjustment of −4.36 percent to maintain overall budget neutrality under the PDGM.

Section III.C. of this final rule with comment period 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 rule finalizes the CY 2020 PDGM case-mix weights and LUPA thresholds for 30-day periods of care. In section III.E. of this final rule, we finalize 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, 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 is 1.5 percent, as required by section 53110 of the BBA of 2018. Section III.F. of this final rule with comment period, finalizes changes change to the fixed-dollar loss ratio to

0.56 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 final rule with comment period, finalized technical regulations correction at § 484.205 regarding split-percentage payments for newly-enrolled HHAs in CY 2020; and finalizes the following additional changes to the split-percentage payment approach: (1) A reduction in the up-front amount paid in response to a Request for Anticipated Payment (RAP) to 20 percent of the estimated final payment amount for both initial and subsequent 30-day periods of care for CY 2020; (2) a reduction to the up-front amount paid in response to a RAP to zero percent of the estimated final payment amount for both initial and subsequent 30-day periods of care with a late submission penalty for failure to submit the RAP within 5 calendar days of the start of care for the first 30-day period within a 60-day certification period and within 5 calendar days of day 31 for the second, subsequent 30-day period in a 60-day certification period for CY 2021; (3) the elimination of the split-percentage payment approach entirely in CY 2022, replacing the RAP with a one-time submission of a Notice of Admission (NOA) with a late submission penalty for failure to submit the NOA within 5 calendar days of the start of care. In section III.H. of this final rule with comment period, we are finalizing our proposal to allow therapist assistants to furnish maintenance therapy under the Medicare home health benefit, and section III.I. of this final rule with comment period, we finalize a change in the payment regulation text at § 409.43 related to home health plan of care requirements for payment.

2. HHVBP

In section IV. of this final rule with comment period, we are finalizing provisions requiring public reporting performance data for Performance Year (PY) 5 of the HHVBP Model. Specifically, we are finalizing the public reporting of 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 final rule with comment period, we are finalizing 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 a requirement for HHAs to report standardized patient assessment data. In section V.J. of this final rule, we are finalizing our proposal to re-designate our current HH QRP regulations in a different section of our regulations and to codify other current policies in that new regulatory section with one substantive change as well as a few technical edits. Finally, in section V.K. of the rule, we are not finalizing the removal of question 10 from all HHCAHPS Surveys (both mail surveys and telephone surveys).

4. Home Infusion Therapy

In section VI.A. of this final rule with comment period, we discuss the general background of home infusion therapy services and how that relates to the implementation of the new home infusion benefit in CY 2021. Section VI.B. of this final rule with comment period discusses the updates to 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 final rule with comment period, we are finalizing our proposal 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. Subpart P includes beneficiary qualifications and plan of care requirements in accordance with section 1861(iii) of the Act. In section VI.D. of this final rule with comment period, we finalize 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 payment categories, amounts, and required and optional payment adjustments. In section VI.E. of this final rule with comment period, we finalize the use of 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 section VI.F. of this final rule with comment period, we summarize comments received on the proposed rule regarding several topics for home infusion therapy services for CY 2021 such as: Optional payment adjustments, prior authorization, and high-cost outliers. In section VI.G. of this final rule with comment period, we discuss billing procedures for CY 2021 home infusion therapy services. Lastly, given the new permanent home infusion therapy benefit to be implemented beginning January 1, 2021, which includes payment for professional services, including nursing, for parenteral drugs administered intravenously or subcutaneously for a period of 15 minutes or more through a pump that is a covered item of DME; we are soliciting comments on options to enhance future efforts to improve policies related to coverage of eligible drugs for home infusion therapy. In response to stakeholder concerns regarding the limitations of the DME LCDs for External Infusion Pumps that preclude coverage to certain infused drugs, we seek comments on the criteria CMS could consider, within the scope of the DME benefit, to allow coverage of additional home infusion drugs.

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 $171.7 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 1.9 percent, or $1.2 million decrease in payments to home infusion therapy suppliers in CY 2020 based on the proposed CY 2020 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 $2 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 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 and these changes are discussed later in this final rule with comment period.

B. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the 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 with comment period (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 with comment period, 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. 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 with comment period (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 (84 FR 34602), we examined FY 2017 HHA cost reports as this is the most recent and complete cost report data at the time of rulemaking. We include this analysis again in this final rule with comment period. 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.

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 (Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates. June 21, 2013. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/Analyses-in-Support-of-Rebasing-and-Updating-the-Medicare-Home-Health-Payment-Rates-Technical-Report.pdf.) using cost reports accessed 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.

[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. In the proposed rule, we estimated the CY 2020 costs by using the home health market basket update of 1.5 percent as required by the BBA of 2018. However, for this final rule with comment period, we believe that we should be consistent with the estimation of cost calculations for purposes of analyzing the payment adequacy. This would warrant the same approach for estimating CY 2020 costs as was used for CYs 2018 and 2019. Therefore, for this final rule with comment period, we calculated the estimated CY 2020 60-day episode costs and 30-day period costs by applying each year's market basket update minus the multifactor productivity factor for that year. For CY 2020, based on IHS Global Inc. 2019 q3 forecast, the home health market basket update is forecasted to be 2.9 percent; the MFP adjustment is forecasted to be 0.3 percent resulting in a forecasted MFP-adjusted home health market basket update of 2.6 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 minus MFP	2020 Estimated 60-Day Costs
Skilled Nursing	$1,198.39	1.019	1.022	1.026	$1,280.47
Physical Therapy	$925.78	1.019	1.022	1.026	$989.19
Occupational Therapy	$266.41	1.019	1.022	1.026	$284.66
Speech Pathology	$60.71	1.019	1.022	1.026	$64.87
Medical Social Services	$31.85	1.019	1.022	1.026	$34.03
Home Health Aides	$106.62	1.019	1.022	1.026	$113.92
Total	$2,589.76	1.019	1.022	1.026	**$2,767.15**

The CY 2020 60-day episode payment will be $3,220.79, approximately 16 percent more than the estimated CY 2020 60-day episode cost of $2,767.15.

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.

Using the same approach as calculating the estimated CY 2020 60-day episode costs, 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 2019, and 2020. 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 Update minus MFP	2019 Market Basket Update minus MFP	2020 Market Basket Update minus MFP	CY 2020 Estimated 30-Day Costs with NRS
Skilled Nursing	$680.81	1.019	1.022	1.026	$727.44
Physical Therapy	$552.59	1.019	1.022	1.026	$590.44
Occupational Therapy	$161.41	1.019	1.022	1.026	$172.47
Speech Pathology	$36.43	1.019	1.022	1.026	$38.93
Medical Social Services	$18.20	1.019	1.022	1.026	$19.45
Home Health Aides	$56.25	1.019	1.022	1.026	$60.10
Total	$1,505.69	1.019	1.022	1.026	$1,608.82

The estimated, budget-neutral 30-day payment for CY 2020 is, $1,824.99 as described in section III.E. of this final rule with comment period. Updating this amount by the CY 2020 home health market basket update of 1.5 percent and the wage index budget neutrality factor results in an estimated CY 2020 30-day payment amount of $1,864.03 (as described in section III.B. of this final rule with comment period) approximately 16 percent more than the estimated CY 2020 30-day period cost of $1,608.82. 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. 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 with comment period (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 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 finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461) and these assumptions are further described in section III.B. of this final rule with comment period.

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 with comment period (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 final rule with comment period effectuates the requirements for the implementation of the PDGM, as well as finalizes 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 with comment period (83 FR 56406) and, as such, there were no new policy proposals in the CY 2020 home health proposed rule on the structure of the PDGM or the change to a 30-day unit of payment. However, there were proposals related to the split-percentage payments upon implementation of the PDGM and the 30-day unit of payment as described in section III.G. of this final rule with comment period.

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.E. of this final rule with comment period, will 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 Figure 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 final rule with comment period (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 final CY 2020 PDGM case-mix weights are listed in section III.D. of this final rule with comment period.

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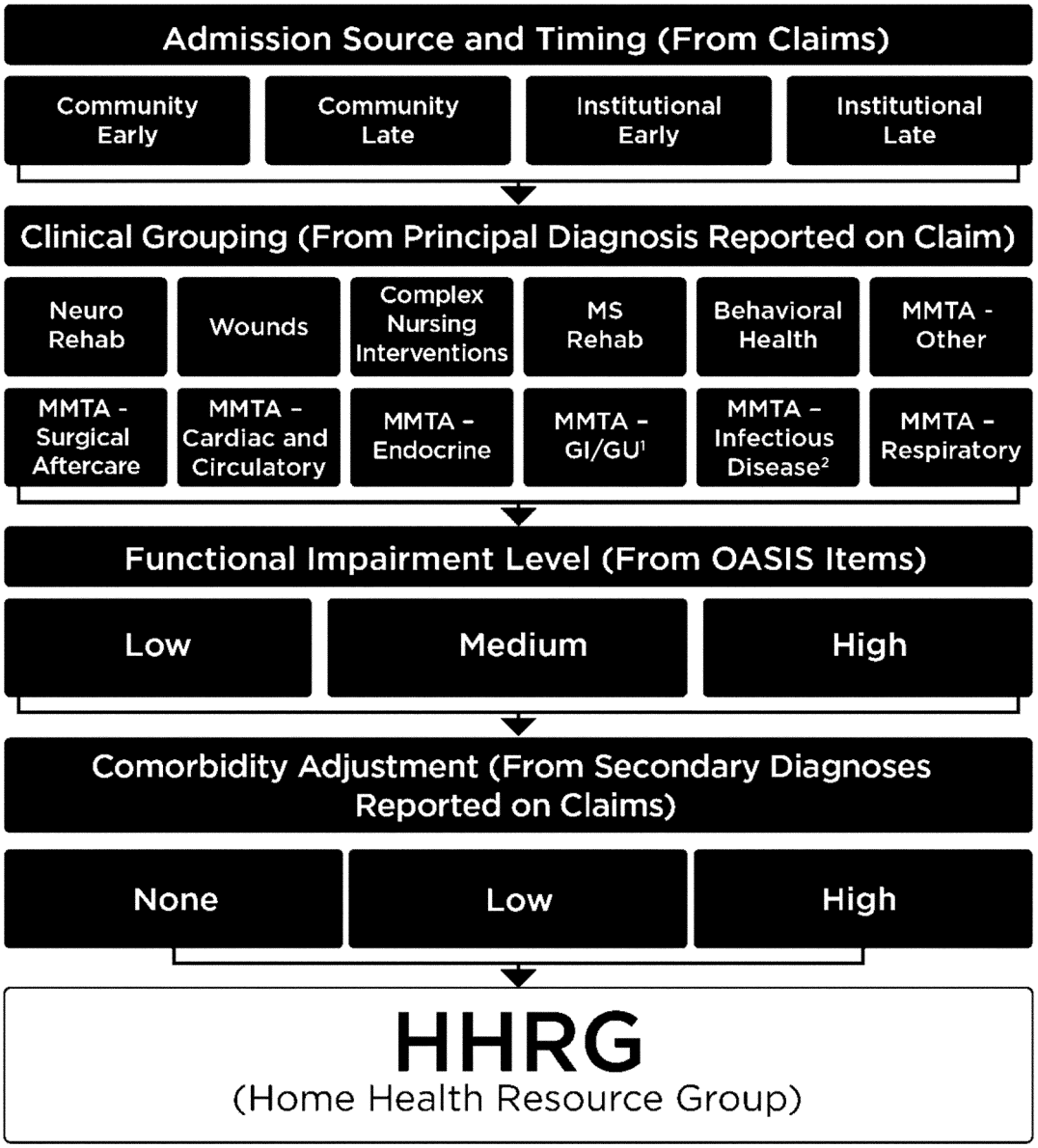
FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



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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 re-certifications 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] has been 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] Home Health (HH) Patient-Driven Groupings Model (PDGM)—Split Implementation Change Request. February 15, 2019. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4244CP.pdf.*

[2] Medicare Claims Processing Manual Chapter 10—Home Health Agency Billing. *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 [3] 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.[4] 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.[5] 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,[6] 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

[3] Home Health Agency (HHA) Interpretive Guidelines. August 31, 2018. *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-25-HHA.pdf.*

[4] State Operations Manual (SOM), Appendix B. *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-25-HHA.pdf.*

[5] Outcome and Assessment Information Set OASIS–D Guidance Manual. January 1, 2019. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D-Guidance-Manual-final.pdf.*

[6] Home Health Conditions of Participation. *https://www.ecfr.gov/cgi-bin/text-idx?SID=fb4353988ab209999ca866efc142a601&mc=true&node=pt42.5.484&rgn=div5.*

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 is included in the Medicare Claims Processing Manual, chapter 10.

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, to accompany this final rule with comment period, we updated 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 PDGM web page (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.html*). This Interactive Grouper Tool includes all of the ICD–10–CM 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. This Interactive Grouper Tool has been provided to assist HHAs in understanding the effects of the transition to the PDGM and will not be updated on an annual basis after CY 2020 as HHAs will have the opportunity download the HH PPS Grouper annually. The final grouper for CY 2020 will be posted with this final rule with comment period and can be found on the following website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/CaseMixGrouperSoftware.html*. Additionally, HHAs can also request a Home Health Claims-OASIS Limited Data Set (LDS) to accompany the CY 2020 HH PPS final rule with comment period 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 CMS Limited Data Set (LDS) Files 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.[7] 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 8 and 9 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 with comment period (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 this CY 2020 HH PPS final rule with comment period, we updated 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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[7] Overview of the Home Health Groupings Model. November 18, 2016. *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	18.0%
	2	5	60.5%
	3	12	21.5%
M1830: Bathing	0 or 1	0	4.6%
	2	3	16.5%
	3 or 4	13	54.0%
	5 or 6	20	24.9%
M1840: Toilet Transferring	0 or 1	0	66.2%
	2, 3 or 4	5	33.8%
M1850: Transferring	0	0	2.5%
	1	3	32.3%
	2, 3, 4 or 5	7	65.3%
M1860: Ambulation/Locomotion	0 or 1	0	6.2%
	2	9	22.5%
	3	11	55.8%
	4, 5 or 6	23	15.4%
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 (as of July 31, 2019).

TABLE 9: CY 2020 THRESHOLDS FOR FUNCTIONAL IMPAIRMENT LEVELS BY CLINICAL GROUP

Clinical Group	Level of Impairment	Points (2018 Data)
MMTA - Other	Low	**0-36**
	Medium	**37-52**
	High	**53+**
Behavioral Health	Low	**0-36**
	Medium	**37-52**
	High	**53+**
Complex Nursing Interventions	Low	**0-38**
	Medium	**39-58**
	High	**59+**
Musculoskeletal Rehabilitation	Low	**0-38**
	Medium	**39-52**
	High	**53+**
Neuro Rehabilitation	Low	**0-45**
	Medium	**46-60**
	High	**61+**
Wound	Low	**0-41**
	Medium	**42-59**
	High	**60+**
MMTA - Surgical Aftercare	Low	**0-37**
	Medium	**38-50**
	High	**51+**
MMTA - Cardiac and Circulatory	Low	**0-36**
	Medium	**37-52**
	High	**53+**
MMTA - Endocrine	Low	**0-34**
	Medium	**35-52**
	High	**53+**
MMTA - Gastrointestinal tract and Genitourinary system	Low	**0-41**
	Medium	**42-54**
	High	**55+**
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	**0-36**
	Medium	**37-52**
	High	**53+**
MMTA - Respiratory	Low	**0-37**
	Medium	**38-52**
	High	**53+**

Source: CY 2018 home health claims and OASIS data (as of July 31, 2019).

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 finalized CY 2020 functional points table and the functional impairment level thresholds table are posted on the HHA Center web page as well as on the PDGM web page.

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 are reported in more than 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.

For CY 2020, there are 13 low comorbidity adjustment subgroups as identified in Table 10 and 31 high comorbidity adjustment interaction subgroups as identified in Table 11.

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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 4	Includes hypertensive heart disease and chronic kidney disease
Circulatory 9	Includes acute and chronic embolisms and thrombosis
Endocrine 2	Includes diabetes with complications
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 (as of July 31, 2019).

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 10	Includes
4	Cerebral 4	Includes sequelae of cerebral vascular diseases	Heart 11	Includes heart failure
5	Cerebral 4	Includes sequelae of cerebral vascular diseases	Neuro 10	Includes peripheral and polyneuropathies
6	Circulatory 4	Includes hypertensive chronic kidney disease	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
7	Circulatory 4	Include hypertensive chronic kidney disease	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
8	Circulatory 4	Include hypertensive chronic kidney disease	Skin 4	Includes Stages Two through Four and Unstageable pressure 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 4	Includes Stages Two through Four and Unstageable pressure ulcers
14	Heart 11	Includes heart failure	Neuro 10	Includes peripheral and polyneuropathies
15	Heart 11	Includes heart failure	Neuro 5	Includes Parkinson's disease
16	Heart 11	Includes heart failure	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis
17	Heart 11	Includes heart failure	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
18	Heart 11	Includes heart failure	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
19	Heart 12	Includes other heart diseases	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
20	Heart 12	Includes other heart diseases	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
21	Neuro 10	Includes peripheral and polyneuropathies	Neuro 5	Includes Parkinson's disease
22	Neuro 3	Includes dementias	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
23	Neuro 5	Includes Parkinson's disease	Renal 3	Includes nephrogenic diabetes insipidus
24	Neuro 7	Includes hemiplegia, paraplegia, and quadriplegia	Renal 3	Includes nephrogenic diabetes insipidus
25	Renal 1	Includes Chronic kidney disease and ESRD	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
26	Renal 1	Includes Chronic kidney disease and ESRD	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
27	Renal 3	Includes nephrogenic diabetes insipidus	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
28	Resp 5	Includes COPD and asthma	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
29	Resp 5	Includes COPD and asthma	Skin 4	Includes Stages Two through Four and Unstageable pressure ulcers
30	Skin 1	Includes cutaneous abscess, cellulitis, lymphangitis	Skin 3	Includes diseases of arteries, arterioles, and capillaries with ulceration and non-pressure, chronic ulcers
31	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 (as of July 31, 2019).

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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 finalized CY 2020 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments are posted on the HHA Center web page as well as on the PDGM web page.

While we did not solicit comments on the PDGM as it was finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we did receive 179 comments on various components of the finalized PDGM from home health agencies, industry associations, as well as individuals. We received a few general comments on the PDGM as a whole. A few comments were received on the admission source case-mix variable, elimination of therapy thresholds, and the comorbidity adjustment; however, the majority of these comments were specific ICD 10–CM code requests to include certain previously excluded diagnosis codes as part of the clinical grouping variable or to move specific diagnosis codes from one clinical group to another. These comments and our responses are summarized in this section of this final rule with comment period.

1. General PDGM Comments

Comment: Several commenters stated they are very encouraged by CMS's efforts to develop a valid and reliable case mix adjustment model that relies on patient characteristics rather than resource use to determine the amount of payment in individual service claims. However, these commenters expressed concern that the PDGM could create financial incentives for home health agencies to under-supply needed care through inappropriate early discharge, improperly limiting the number of visits or types of services provided, or discouraging serving individuals with longer-term needs and people without a prior institutional stay. A commenter recommended that CMS monitor these issues and quality of care during initial implementation of the PDGM in ways that will allow CMS to quickly understand and address emerging problems affecting the provision of home health services. This commenter also suggested that CMS educate home health agencies as well as beneficiaries and their family caregivers about the need for beneficiaries to receive high-quality home health care that meets each Medicare beneficiary's unique needs. Other suggestions included requiring agencies to provide clear, accurate information about what Medicare covers and beneficiary appeal rights and updating CMS educational materials for beneficiaries to assist in this effort. Another commenter urged CMS to be transparent about its education budget and include information about the different mechanisms it will use for the education of providers, beneficiaries, and their family caregivers (as appropriate).

Response: We appreciate commenter support of a case-mix system based on patient-characteristics and other clinical information, rather than one based on the volume of services provided. We agree that this is a more accurate way to align payment with the cost of providing care. However, we recognize stakeholder concerns about possible perverse financial incentives that could arise as a result of transitioning to a new case-mix adjustment methodology and a change in the unit of payment. We reiterate that we expect the provision of services to be made to best meet the patient's care needs and in accordance with the home health CoPs at § 484.60 which sets forth the requirements for the content of the individualized home health plan of care which includes the types of services, supplies, and equipment required; the frequency and duration of visits to be made; as well as patient and caregiver education and training to facilitate timely discharge. Therefore, we do not expect HHAs to under-supply care or services; reduce the number of visits in response to payment; or inappropriately discharge a patient receiving Medicare home health services as these would be violations of the CoPs and could also subject HHAs to program integrity measures.

We also note that the home health CoPs at § 484.50(c) set forth patient rights, which include the patient's right to be involved in the plan of care, the right to be informed of any changes to the plan of care, as well as expected coverage, and possible beneficiary financial liability. Therefore, HHAs are already tasked with informing beneficiaries as to their rights and coverage under the Medicare home health benefit. Moreover, CMS does routinely update its public materials to ensure relevant stakeholders are informed of any policy, coverage, or payment changes. This includes updates to the Medicare Benefit Policy Manual, the ''Medicare and You'' Handbook, ''Medicare's Home Health Benefit'' booklet, and MLN Matters® articles on various aspects of the home health benefit. As with any policy, coverage, or payment change, we will update the necessary public information to ensure full transparency and to provide ample resources for beneficiaries and their families, as well as for home health agencies. The goal of the PDGM is to more accurately align home health payment with patient needs. We note that each individual policy change does not have a corresponding individual educational budget connected with its implementation; therefore this is not information we can provide. We acknowledge that the change to a new case-mix system may have unintended consequences through shifts in home health practices. However, in the CY 2020 HH PPS proposed rule, we stated that we expect the provision of services to be made to best meet the patient's care needs and in accordance with existing regulations. 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.

Comment: A commenter stated that under the current HH PPS, HHAs' costs are ''frontloaded'' and incurred regardless of whether a second 30-day period occurs within a 60-day episode. This commenter stated that CMS should account for these costs and allocate payment weights more toward the first 30-day period in each 60-day episode to ensure that payments are accurately aligned with resource use. Commenters express several concerns with the use of cost report data rather than Bureau of Labor Statistics (BLS) wage data to account for the cost of therapy services; thus, commenters recommend CMS use BLS wage-weighted minutes instead of the approach finalized in the CY 2019 final rule with comment period.

Response: We note that we provided detailed analysis on the estimated costs of 30-day periods of care using a cost-per-minute plus non-routine supply (CPM + NRS) approach in the CY 2019 HH PPS proposed rule (83 FR 32387). We also provided analysis on the average resource use by timing where early 30-day periods have higher resource use that later 30-day periods (83 FR 32392). Likewise, in the CY 2019

HH PPS final rule with comment period (83 FR 56471), we finalized the admission source case-mix variable under the PDGM where ''early'' 30-day periods of care receive a higher payment than ''late'' 30-day periods of care. Commenters supported this payment differential as it more accurately reflects HHA costs that are typically higher during the first 30-day period of care, compared to later 30-day periods of care.

When we finalized the CPM+NRS approach to calculating the costs of care in the CY 2019 HH PPS final rule with comment period, we stated that we believe that the use of HHA Medicare cost reports better reflects changes in utilization, provider payments, and supply amongst Medicare-certified HHAs that occur over time. Under the Wage-Weighted Minutes of Care (WWMC) approach, using the BLS average hourly wage rates for the entire home health care service industry does not reflect changes in Medicare home health utilization that impact costs, such as the allocation of overhead costs when Medicare home health visit patterns change. Using data from HHA Medicare cost reports better represents the total costs incurred during a 30-day period (including, but not limited to, direct patient care contract labor, overhead, and transportation costs), while the WWMC method provides an estimate of only the labor costs (wage and fringe benefit costs) related to direct patient care from patient visits that are incurred during a 30-day period.

Comment: A commenter suggested an additional alternative to consider regarding the implementation of the PDGM. Specifically, this commenter suggested a potential pilot program to test not only the PDGM but possibly the PDPM payment system for skilled nursing facilities to consider some form of a post-acute bundle with shared savings.

Response: We appreciate the commenter's suggestions for innovative ways to improve the health care system and payment models. However, we note that the change in the unit of payment and the case-mix methodology is mandated by the BBA of 2018, as such we are required to implement such changes beginning on January 1, 2020.

2. Admission Source

Comment: A commenter stated that it appears counterintuitive to have a different reimbursement for community versus institutional admission source stating that the goal of home health care is to keep the patients out of the hospital. A commenter expressed concern that even though the application of an admission source measure may seem warranted given data demonstrating different resource use, doing so may incentivize agencies to give priority to post-acute patients over those who are admitted from the community. This commenter stated that the financial impact of the PDGM admission source measure also highlights the inherent weakness of all the other PDGM measures. A few commenters supported the admission source as an indicator of predicted home health resource use.

Response: We agree that the provision of home health services may play an important role in keeping patient's out of the hospital, whether the patient is admitted to home health from an institutional source or from the community. However, the payment adjustments associated with the PDGM case-mix variables are based on the cost of providing care. As described in the CY 2018 HH PPS proposed rule (82 FR 35311), our analytic findings demonstrate that institutional admissions have significantly higher average resource use when compared with community admissions, which ultimately led to the inclusion of the admission source category within the framework of the alternative case-mix adjustment methodology refinements. Additionally, in the CY 2018 HH PPS proposed rule (82 FR 35309), we stated that in our review of related scholarly research, we found that beneficiaries admitted directly or recently from an institutional setting (acute or post-acute care (PAC)) tend to have different care needs and higher resource use than those admitted from the community, thus indicating the need for differentiated payment amounts. Furthermore, in the CY 2018 proposed rule, we provided detailed analysis and research to support the inclusion of an admission source category for case-mix adjustment. We continue to believe that having a case-mix variable accounting for admission source is clinically appropriate, will address the more intensive care needs of those admitted to home health from an institutional setting, and will more accurately align payment with the cost of providing home health care.

To address concerns that the admission source variable may create the incentive to favor institutional admission sources, we fully intend to monitor provider behavior in response to the new PDGM. As we receive and evaluate new data related to the provision of Medicare home health care under the PDGM, we will reassess the appropriateness of the payment levels for all of the case-mix variables, including admission source, to determine if HHAs are inappropriately changing their behavior to favor institutional admission sources over community. Additionally, we will share any concerning behavior or patterns with the Medicare Administrative Contractors (MACs) and other program integrity contractors, if warranted. We plan to monitor and identify any variations in the patterns of care provided to home health patients, including both increased and decreased provision of care to Medicare beneficiaries. We remind stakeholders that the purpose of case-mix adjustment is to align payment with the costs of providing care. As such, certain case-mix variables may have a more significant impact on the payment adjustment than others. However, the case-mix variables in the PDGM work in tandem to fully capture patient characteristics that translate to higher resource needs. The overall payment for a home health period of care under the PDGM is determined by the cumulative effect of all of the variables used in the case-mix adjustments. Ultimately, the goal of the PDGM is to provide more accurate payment based on the identified resource use of different patient groups.

3. Therapy Thresholds

Comment: A few commenters disagreed with the elimination of the therapy thresholds and expressed concern that the PDGM design will have a negative impact on patients who need therapy services and the HHAs that provide it. A commenter stated that therapy services are extraordinarily valuable in the care of Medicare home health beneficiaries and should be supported to the greatest degree possible. Another commenter suggested elimination of the 30-day therapy reassessment requirement stating this would duplicative and unnecessary under PDGM, given that therapy visits are no longer a payment driver, and that all visits must continue to demonstrate a skilled need, independent of a formal reassessment. Many commenters urge CMS to monitor the effects of PDGM and the implications on therapy utilization due to concerns therapy would be underutilized, which could result in beneficiaries going to inpatient settings rather than receiving care at home. Some commenters recommend further analysis to compare utilization of therapy revenue codes under the PPS and PDGM. In addition, commenters encourage CMS to use the survey process to ensure that beneficiaries continue to receive the appropriate level of therapy that were medically

necessary in order to treat or manage the condition.

Response: We agree that therapy remains a valuable service for Medicare home health beneficiaries. In response to the CY 2018 and 2019 HH PPS proposed rules, the majority of commenters agreed that the elimination of therapy thresholds was appropriate because of the financial incentive to overprovide therapy services. While the functional impairment level adjustment in the PDGM is not meant to be a direct proxy for the therapy thresholds, the PDGM has other case-mix variables to adjust payment for those patients requiring multiple therapy disciplines or those chronically ill patients with significant functional impairment. We believe that also accounting for timing, source of admission, clinical group (meaning the primary reason the patient requires home health services), and the presence of comorbidities will provide the necessary adjustments to payment to ensure that care needs are met based on actual patient characteristics. Furthermore, services are to be provided in accordance with the home health plan of care established and periodically reviewed by the certifying physician. Therefore, we expect that home health agencies will continue to provide needed therapy services in accordance with the CoPs at § 484.60, which state that the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. Upon implementation of the PDGM, we will monitor home health utilization, including the provision of therapy services. Finally, we remind commenters that section 51001(a)(3)(B) of the BBA of 2018 prohibits the use of therapy thresholds as part of the overall case-mix adjustment for CY 2020 and subsequent years. Consequently, we have no regulatory discretion in this matter.

While we appreciate commenter suggestions to further reduce burden by eliminating therapy reassessments, we did not propose to eliminate the current 30-day therapy reassessment requirement at § 409.44(c)(2)(i)(B) in the CY 2020 HH PPS proposed rule. When we finalized the 30-day therapy reassessment requirement in the CY 2015 HH PPS final rule (79 FR 66103), we stated that the qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs. Furthermore, in the CY 2015 final rule, the overwhelming majority of commenters recommended reassessing the patient at least once every 30 days as the most appropriate time frame. Commenters stated that a 30 day reassessment timeframe aligns with many state practice acts, which require that a therapist reassess the patient at least once every 30 days. As part of our response, we also referenced the American Physical Therapy Association (APTA) guidelines which state that at least once a month, the qualified therapist should conduct a supervisory visit with the therapist assistant which should include: An on-site reexamination of the patient/client; on-site review of the plan of care with appropriate revision or termination; and evaluation of need and recommendation for utilization of outside resources.[8] We also stated that we believe that requiring therapy reassessments at least once every 30 days, the CoP requirements regarding the plan of care, and the APTA guidelines together promote regular interaction between the therapist and the patient. However, we recognize the importance of decreasing unnecessary burden and we will continue to monitor home health utilization, including the provision of therapy visits, to re-evaluate any existing policies to determine if any additional changes should be proposed in future rulemaking. Likewise, we understand commenter concerns about potential underutilization of certain disciplines, especially therapy, with the elimination of therapy thresholds. The home health CoPs have requirements as to the content of the home health plan of care, as well as providing services that are ordered by the physician as indicated in the plan of care. Therefore, existing survey mechanisms are in place to help ensure patient safety and quality standards. However, as we noted in the CY 2019 HH PPS final rule with comment period, upon implementation of the PDGM, we will continue to monitor the payment system as we have done since the inception of the benefit. We will closely monitor patterns related to utilization, including changes in the composition of patients receiving the home health benefit and the types and amounts of services they are receiving, as well as any changes in the settings of care.

Comment: A few commenters support the elimination of therapy as the driver of payment and offered historical context to the potential increase in therapy utilization as it relates to the Home Health Quality Reporting Program. A commenter also identified potential opportunity for oversight and monitoring to address ''problematic HHAs'' that the commenter identifies as driving the therapy utilization data since the inception of the HH PPS. Another commenter stated that the elimination of therapy volumes as a determinant of reimbursement is appropriate and that they anticipate the clinical groupings based on diagnosis, along with the comorbidity adjustments will prove to be acceptable elements of payment.

MedPAC also supports the elimination of therapy as a payment factor because their March 2018 Report to Congress[9] stated concerns about the financial incentive to providing more therapy that is not necessarily tied to patient characteristics, which is a recognized vulnerability in the HH PPS. However, MedPAC believes additional monitoring is necessary regarding the 30 day payment to understand whether there is a new incentive for HHAs to provide just enough services/visits to surpass the threshold for a second 30 day payment.

Response: We appreciate commenter support regarding the elimination of the therapy thresholds for use in adjusting home health payment. We believe that elimination of the therapy thresholds is more in alignment with the intent of the home health benefit to be patient-centered and based on patient characteristics, such as functional status, and actual patient needs. Likewise, we expect that any services provided would be in accordance with all Federal and State laws, including all licensure requirements. The provision of skilled therapy services as part of a home health plan of care must also adhere to the home health CoPs, (42 CFR 484.60). We believe that the elimination of the therapy thresholds will remove the financial incentive to provide therapy solely for increased payment. Upon implementation of the PDGM and the 30-day unit of payment, we will continue to monitor home health utilization, including the provision of therapy services, as well as any shifts in disciplines to determine if

[8] Direction and Supervision of the Physical Therapist Assistant. August 30, 2018. *http://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Practice/DirectionSupervisionPTA.pdf.*

[9] MedPAC Report to Congress, Home health care services, March 2018. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch9_sec.pdf?sfvrsn=0.*

any program integrity or survey efforts may be warranted.

4. Non-Routine Supplies (NRS)

Comment: A couple of commenters suggested that CMS should consider the higher costs of wound care supplies and should pay more for such supplies as part of the PDGM. Another commenter recommended that the cost of non-routine supplies (NRS) should be included in outlier payments.

Response: As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), similar to the current system, NRS still would be paid prospectively under the PDGM, but the PDGM eliminates the separate case-mix adjustment model for NRS. We believe that the PDGM offers an alternative method for accounting for NRS costs and payments by grouping patients more likely to require high NRS utilization. Under the PDGM, NRS costs are reflected in the average resource use that drives the case-mix weights. If there is a high amount of NRS cost for all periods in a particular group (holding all else equal), the resource use for those periods will be higher relative to the overall average and the case-mix weight will correspondingly be higher. We appreciate the commenters' suggestion regarding the inclusion of supplies in the outlier calculation under the PDGM. In order to incorporate supply costs into the outlier calculation, significant claims payment systems modifications would be required. However, after implementation of the PDGM, we will continue to monitor the provision of NRS and we will consider whether to add supply costs to the outlier calculations and evaluate whether such a policy change is appropriate for future rulemaking.

5. Clinical Groups

Comment: Some commenters made general remarks regarding the diagnosis codes included in the clinical grouping case-mix variable. A few commenters state that elimination of certain diagnosis codes would narrow the home health benefit and may prevent access to care to which Medicare beneficiaries are legally entitled. Another commenter stated that the coding-related proposals could limit the home health benefit for eligible beneficiaries in need of skilled maintenance therapy. A commenter stated that the removal of certain diagnosis codes from the clinical grouping would essentially eliminate coverage for skilled services under the home health benefit and said that CMS should not finalize elimination of these codes and should recalculate rates with all existing codes included.

Response: The elimination of certain diagnosis codes from the HH PPS Grouper is not unique to the PDGM as we have previously removed codes from the 153-group HH PPS case-mix system that no longer have a significant impact on resource use. As stated previously, the clinical grouping is only one case-mix variable in the PDGM. These clinical groups are designed to capture the most common types of care that HHAs provide. Although the principal diagnosis code is the basis for the clinical grouping, secondary diagnosis codes and patient characteristics will be used to case-mix adjust the period further through the comorbidity adjustment and functional level. We believe that the PDGM has a robust set of clinical characteristics to ensure that payment accurately aligns with patient needs and therefore, we do not expect there to be any issues with patient access to home health services. Furthermore, eligibility for home health services remains the same as under the 153-group system. That is, individuals are eligible for home health services if the following criteria are met: The individual is confined to the home; is under the care of a physician; is receiving services under a plan of care established and periodically reviewed by a physician is in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology therapy; has a continuing need for occupational therapy. Therefore, a patient's principal or secondary diagnoses are not sole factors in whether a patient is eligible for Medicare home health services. As such, eligible beneficiaries are entitled to their Medicare home health benefits and we do not expect there to be an access to care issue. With respect to the provision of therapy services as they relate to the home health period's clinical group, we should emphasize that although the principal diagnosis is a contributing factor in the PDGM and determines the clinical group, it is not the only consideration in determining what home health services are needed in a patient's care plan. We stated in the CY 2019 HH PPS proposed rule (83 FR 32401), that it is the responsibility of the patient's treating physician to determine if and what type of therapy (that is, maintenance or otherwise) the patient needs regardless of clinical grouping. As such, we continue to expect the ordering physician, in conjunction with the therapist, to develop and follow a plan of care for any home health patient, regardless of clinical group, as outlined in the skilled service requirements when therapy is deemed reasonable and necessary. Therefore, a home health period's clinical group should not solely determine the type and extent of therapy needed for a particular patient.

As described in the CY 2018 HH PPS proposed rule (82 FR 35313), to inform the development of the clinical groups, our home health contractor, Abt Associates and CMS conducted an extensive review of diagnosis codes to identify the primary reasons for home health services under the Medicare home health benefit. The published HHGM (predecessor to the PDGM), technical report from December 2016 [10] and the CY 2018 HH PPS proposed rule (82 FR 35314), detail several reasons why a diagnosis code was not assigned to one of the clinical groups. These included if the diagnosis code was too vague, meaning the code does not provide adequate information to support the need for skilled home health services (for example H57.9, Unspecified disorder of eye and adnexa); the code is subject to laterality for which the home health clinician could assess the appropriate side (for example, some diagnosis codes indicate laterality, specifying whether the condition occurs on the left or right, or is bilateral); the code, based on ICD 10–CM, American Hospital Association (AHA) Coding Clinic, or Medicare Code Edits (MCE) would indicate a non-home health service (for example, dental codes); the code is a manifestation code subject to a manifestation/etiology convention, meaning that the etiology code must be reported as the principal diagnosis, or the code is subject to a code first sequencing convention (for example, G99.2 myelopathy in diseases classified elsewhere); the code identifies a condition which would be unlikely to require home health services (for example, L81.2, Freckles); the code is restricted to the acute care setting per ICD 10–CM/AHA Coding Clinic, or the diagnosis indicates death as the outcome (for example S06.1X7A, Traumatic cerebral edema with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness). Overall, we continue to believe that the PDGM clinical grouping includes a robust set of diagnosis codes and includes more codes than under clinical dimension of the 153-group case-mix system. Therefore, this should afford HHAs greater opportunity to more fully describe patient characteristics through

[10] ''Overview of the Home Health Groupings Model'' Technical Report. November 18, 2016. *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

principal and secondary diagnosis reporting on home health claims.

While there are certain diagnosis codes that are not assigned to a clinical group under the PDGM for the reasons described, we remind commenters that claims submitted with such codes are not denied; rather they are returned to the provider for more definitive coding. The importance of consistent, complete medical documentation cannot be overemphasized. Without such documentation, accurate diagnosis coding cannot be achieved; therefore, ICD–10–CM coding guidelines [11] state that the entire record should be reviewed to determine the specific reason for the encounter and the conditions treated. We remind stakeholders that if there is a question as to what the appropriate principal (or secondary) diagnosis should be, the HHA should query the certifying physician who is responsible for establishing the home health plan of care.

Comment: One industry association stated it had a workgroup conduct some analysis on the diagnosis codes and their assigned clinical groups and they state that it was discovered that in a significant number of instances a code assigned to one clinical grouping was also placed in a different clinical grouping. They noted that in every case they analyzed where a code was assigned to a different clinical grouping, it was assigned to the Complex Nursing group. The commenter requested clarification and CMS' rationale so they could share with other industry stakeholders.

Response: We remind commenters that in developing the case-mix weights for the PDGM, we examined the principal diagnosis codes reported by HHAs and, in order to assign periods of care into the appropriate clinical group representing the primary reason for home health services, we also looked at OASIS item, M1030, ''Therapies'' (identifies whether the patient is receiving intravenous, parenteral nutrition or enteral nutrition therapy at home) to see if home health patients were receiving complex therapies for which the appropriate case-mix adjustment should be made. Therefore, for those circumstances in which the workgroup's analysis of the principal diagnosis would have grouped the period of care into one of the MMTA subgroups, but the actual period was grouped into Complex Nursing Interventions, this is likely due to that period of care being assigned based on the response to OASIS item M1030, reflecting complex nursing interventions provided during the course of home health care. However, we note that for implementation of the PDGM in CY 2020 and subsequent years, we have assigned ICD–10–CM diagnosis codes to the Complex Nursing Interventions group that reflect these more complex therapies previously identified from the OASIS item M1030 (for example, Z45.2, Encounter for adjustment and management of venous access device) and we will be using the diagnosis codes reported on the home health claim and not OASIS items to assign a period of care to a clinical group for case-mix adjustment purposes.

Comment: Several commenters stated that symptom codes should be allowed to be reported as the principal diagnosis and assigned to a clinical group. A few commenters stated that disallowing symptom codes for principal diagnosis consideration will cause HHAs to report a principal diagnosis that would not truly represent the reason for the home health encounter and would force HHAs to ''upcode''. A commenter remarked that there is a significant portion of the elderly population who exhibit symptomology but have declined further testing or the medical community has decided not to order expensive tests since many times the treatment remains the same. Several symptom codes were specifically mentioned for inclusion in the clinical group variable by a national industry association, as well as HHAs. Commenters suggested that the following symptom codes should be in the MS Rehab clinical group:

- R26.89, Other abnormalities of gait and mobility
- R29.6, Repeated falls

The following symptom codes were suggested to be included in the clinical group variable, but without a recommendation for a specific PDGM clinical group:

- R00.1, Bradycardia
- R41.82, Altered Mental Status
- R42, Dizziness and giddiness.

And, several commenters suggested the following symptom codes should be in the Neuro Rehab clinical group:

- R27.0, Ataxia, unspecified
- R13.10, Dysphagia

Response: As we have stated in the CY 2020 proposed rule and this final rule with comment period, we do not support or condone coding solely for purposes of higher payment (what commenters refer to as ''upcoding''). In accordance with ICD–10–CM coding guidelines, the principal diagnosis reported is that ''condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.'' For purposes of home health care admission, this would be the diagnosis chiefly responsible for home health services. Because of the home health requirements that the individual receiving home health services must be certified for such services and must have had a face-to-face encounter related to the primary reason for home health care, we believe that by the time an individual is admitted to home health, the patient has been seen by other health care providers and a diagnosis has been established. We note that we adopted a similar position as it relates hospice diagnosis reporting. In the FY 2014 hospice proposed rule (78 FR 27831), we stated that if a nonspecific, ill-defined symptom diagnosis is reported as the principal hospice diagnosis, a comprehensive, individualized patient-centered plan of care, as required, may be difficult to accurately develop and implement, and, as a result, the hospice beneficiary may not receive the full benefit of hospice services. We believe that the same principle applies to home health beneficiaries and that accurate documentation and diagnosis reporting is essential to ensure that an individualized plan of care is established to meet the patient's home health needs. Furthermore, the ICD–10–CM coding guidelines state that codes for symptoms, signs, and ill-defined conditions are not to be used as the principal diagnosis when a related definitive diagnosis has been established. Therefore, because of the inclusion of a clinical group for case-mix adjustment purposes predicated on diagnosis reporting, we believe that HHAs would improve their overall documentation and accuracy of their diagnosis code reporting to reflect patient characteristics defined by diagnosis codes, as well as other important patient information that reflects resource utilization (for example functional impairment). As such, we believe that the reporting of ill-defined symptom codes as the principal diagnosis would be less frequent.

As we stated in the CY 2019 HH PPS final rule with comment period (83 FR 56473), we believe that the majority of the R-codes (codes that describe signs and symptoms, as opposed to diagnoses) are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups. We

[11] ''ICD–10–CM Official Guidelines for Coding and Reporting FY 2020 (October 1, 2019–September 30, 2020). *https://www.cms.gov/Medicare/Coding/0ICD10/Downloads/2020-Coding-Guidelines.pdf.*

believe that the use of symptoms, signs, and abnormal clinical and laboratory findings would make it difficult to meet the requirements of an individualized plan of care as required at § 484.60. Likewise, we believe that clinically it is important for home health providers to have a clear understanding of the patients' diagnoses in order to safely and effectively furnish home health services. Interventions and treatment aimed at mitigating signs and symptoms of a condition may vary depending on the cause. For example, if a patient has been referred to home health with a diagnosis of ''other abnormalities of gait and mobility'' (R26.89), we believe it is important for the home health clinician to know what is precipitating the abnormality. For instance, a plan of care for a gait abnormality related to a neurological diagnosis is likely to be different from a plan of care for a gait abnormality due to a fracture or injury. Anecdotally, we have heard that the home health referral may be non-specific or that the physician may be in the process of determining a more definitive diagnosis. However, with respect to patient safety and quality of care, we believe it is important for a clinician to investigate the cause of the signs and/or symptoms for which the referral was made. This may involve calling the referring physician to gather more information regarding the gait abnormality. We note that HHAs are required under the home health CoPs at § 484.60 to participate in care coordination to assure the identification of patient needs and factors that could affect patient safety and treatment efficacy. ICD–10–CM coding guidelines are clear that R-codes are to be used when no more specific diagnosis can be made even after all the facts bearing on the case have been investigated. Therefore, these codes should not be used as a principal diagnosis for the provision of home health services while a physician may still be in the diagnostic process. By the time the patient is referred to home health and meets the qualifications of eligibility, we would expect that a more definitive code would substantiate the need for services. Furthermore, commenters have indicated a preference for greater specificity in the clinical groups, therefore, we believe this should extend to the codes within the clinical groups as well.

Regarding commenters suggesting that R29.6, Repeated falls, be included in the MS Rehab group, we note that ICD–10–CM coding guidelines state to only use R29.6 for use for encounters when a patient has recently fallen and the reason for the fall is being investigated. Given that the patient must be certified for home health services and must have had a face-to-face encounter related to the primary reason for home health services, we do not believe that this particular symptom code would be appropriate for the principal diagnosis to substantiate home health services. We believe that by the time a home health referral is made, a more clearly defined diagnosis would have been established to more accurately describe the patient's condition. However, if the patient's condition has resulted in repeated falls, the HHA would report Z91.81, History of falling, as a secondary diagnosis to describe that the patient has fallen in the past and is at future risk for falls to more accurately describe the patient's need for home health services. For the same reasons as stated throughout this response, we do not believe it appropriate to include R00.1 Bradycardia, R41.82, Altered Mental Status, or R42, Dizziness and giddiness as part of the clinical group case-mix variable because of the vague nature of symptom codes where there could be multiple reasons for such symptoms. In order to develop an appropriate, individualized home health plan of care, we believe it is clinically essential to understand the causes of such symptoms to safely and effectively provide home health services. Furthermore, it has been our longstanding policy to avoid vague diagnoses for reporting and payment purposes. Specifically, we stipulated in the 2008 HH PPS final rule (72 FR 49774) that the case-mix system avoid, to the fullest extent possible, non-specific or ambiguous ICD–9–CM codes, codes that represent general symptomatic complaints in the elderly population, and codes that lack consensus for clear diagnostic criteria within the medical community. We note that diagnosis codes R00–R99 include symptoms, signs, abnormal results of clinical or other investigative procedures, and ill-defined conditions are limited for those circumstances where there is no recorded diagnosis that is classifiable elsewhere. However, patients are referred to home health from other clinical settings (either from a facility or a community-based provider) and therefore, we believe that the medical records from such referral source should provide information as to the need for home health services, including the diagnoses established by such providers. Clinically, this information is needed to develop the individualized plan of care with patient-specific goals. In the circumstance where such information is missing or insufficient, we believe that HHAs should query these referring providers to ensure they have a clear understanding of the conditions affecting patients in need of home health services.

Regarding suggestions to include the symptom codes R27.0, Ataxia, unspecified, and R13.10, Dysphagia, in the Neuro Rehab clinical group, we reiterate our position as noted previously—that by the time a patient is admitted for home health services, there should be sufficient documentation in the patient's medical record to have an established diagnosis, and that a symptom diagnosis should not be reported as the principal diagnosis as this could be the result of other conditions besides a neurological condition and therefore, grouping the period of care into Neuro Rehab may not be appropriate. We continue to believe that the home health clinician needs appropriate, accurate clinical information, including the cause of such symptoms, in order to develop an individualized plan of care to specify the services necessary to meet the patient-specific needs.

However, we analyzed the frequency of the reporting of each of these diagnoses and we note that in 2018, there were only 3,461 30-day periods in which R27.0, Ataxia, unspecified, was reported as the principal diagnosis. However, in looking at the reported secondary diagnoses accompanying this principal diagnosis, HHAs reported established diagnoses that could explain the reason for the unspecified ataxia and would group the 30-day period of care into the Neuro Rehab group. For example, we found reported secondary diagnoses of Alzheimer's disease, Parkinson's disease, and polyneuropathy. Given that symptom diagnoses should not be reported as the principal diagnosis if there is an established diagnosis, we believe that the established diagnosis would be reported first, and the symptom code, unspecified ataxia, would be reported as a secondary diagnosis to fully reflect patient characteristics. Furthermore, in reviewing the tabular index in the CY 2020 ICD–10–CM official code set [12] for ''ataxia'', there are multiple diagnosis codes available to more accurately describe the underlying condition causing the ataxia. We also note that ''unspecified'' codes should only be reported when the medical record is

[12] 2020 ICD–10–CM web page. *https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM.html.*

insufficient to assign a more specific code.

We also analyzed the frequency of reporting of R13.10, dysphagia, unspecified and we note that in 2018, there were approximately 28,000 30-day periods in which this particular code was reported as the principal diagnosis. In looking at the reported secondary diagnoses accompanying this principal diagnosis, we found that while there were incidences where there were other reported diagnoses which could explain the reason for the dysphagia, more often than not, there was no clear clinical picture of the possible etiology where a different reported principal diagnosis would signal the need for therapy. Furthermore, we received comments on this particular diagnosis stating that while there are diagnosis codes for dysphagia resulting from a cerebrovascular event (for example, stroke) and others resulting from somatoform disorders (for example, psychogenic dysphagia), there are very few disease-specific diagnosis codes to identify associated dysphagia (for example, dysphagia resulting from throat cancer treatment). A review of the CY 2020 ICD–10–CM official code set tabular index, showed that the majority of codes to describe dysphagia are the R13 codes. We recognize that dysphagia codes associated with a cerebrovascular event would be assigned to the Neuro Rehab clinical group and commenters stated that those patients with dysphagia due to etiologies not associated with cerebrovascular events would most often require speech-language pathology therapy if the primary reason for home health services is for the dysphagia. Given the current lack of other definitive diagnoses to describe certain forms of dysphagia, we agree that the R-codes to describe dysphagia would be acceptable for reporting the primary reason for home health services. Therefore, we will assign the following R-codes to the Neuro Rehab clinical group:

- R13.10, Dysphagia, unspecified
- R13.11, Dysphagia, oral phase
- R13.12, Dysphagia, oropharyngeal phase
- R13.13 Dysphagia, pharyngeal phase
- R13.14, Dysphagia, pharyngoesophageal phase
- R13.19, Other dysphagia

While we understand that dysphagia could be the result of non-neurological conditions, we are assigning these dysphagia groups to the Neuro Rehab group as we believe the intensity of speech-language pathology therapy would be similar to those suffering from dysphagia resulting from a neurological condition. However, we will monitor the use of these dysphagia R-codes to determine their impact on resources utilization and whether any future changes would be warranted.

Finally, we remind commenters that ICD–10–CM coding guidelines state that codes for signs and symptoms may be reported in addition to a related definitive diagnosis when the sign or symptom is not routinely associated with that diagnosis, such as signs and symptoms associated with complex syndromes. The definitive diagnosis should be sequenced before the symptom code. Signs or symptoms that are associated routinely with a disease process should not be assigned as secondary codes, unless otherwise instructed by the classification. Therefore, we expect that HHAs would report the principal and secondary diagnoses that affect the home health plan of care and justify the need for home health services.

Comment: We received specific coding comments from national industry associations as well as well as from other HHAs, with recommendations to change or add the following codes to the clinical group variable.

Response: Table 12 lists these codes and the commenters recommended clinical group, as well as our response to these recommendations:

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TABLE 12: COMMENTER RECOMMENDATIONS AND CMS RESPONSES FOR SPECIFIC CLINICAL GROUP CHANGES

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy w/o gangrene	MMTA-Endo	Commenters recommended assigning to the Wound group as they stated that venous insufficiency in a patient with diabetes is assumed to be a diabetic angiopathy.	We disagree with this recommendation because these two conditions are not synonymous. However, we will continue to examine reported diagnosis codes, and the associated resource use to determine if any future changes to coding assignments are warranted.	MMTA-Endo
E11.9	Type 2 diabetes mellitus without complications	MMTA-Other	Commenters recommended assigning to MMTA-Endo as they stated that if listed this diagnosis code was primary, this would mean that the patient is newly diagnosed.	We agree with commenters that this code should be grouped under the MMTA-Endo group. Furthermore, to be clinically consistent, we will also move E10.9, E11.9, and E13.9 to MMTA-Endo as well.	MMTA-Endo
I87.2	Venous Insufficiency (chronic/peripheral)	MMTA-Cardiac	Commenters recommended assigning to the Wound group.	We agree with commenters that this should be grouped under Wound as the ICD-10 Index entry for Ulcer, Stasis (venous) lists I87.2 as the appropriate diagnosis code to report.	Wound
I87.311 I87.312 I87.313 I87.331 I87.332 I87.333	Chronic venous hypertension w ulcer of right low extremity Chronic venous hypertension w ulcer of left low extremity Chronic venous hypertension w ulcer of bilateral low extremity Chronic venous hypertension w ulcer and inflammation of r low extremity Chronic venous hypertension w ulcer and inflammation of l low extremity Chronic venous hypertension w ulcer and inflammation of bilateral low extremity	MMTA-Cardiac	Commenters recommended assigning to the Wound group because of the code description.	We agree with commenters that this should be grouped under the Wound group given the ulcer is included in the code description.	Wound

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
J9501 J9502 J9503 J9504 J9509	Hemorrhage from tracheostomy stoma Infection of tracheostomy stoma Malfunction of tracheostomy stoma Tracheo-esophageal fistula following tracheostomy Other tracheostomy complication	MMTA-Resp	Commenters recommended that all complications of ostomies be included in the Complex group.	We agree with commenters that this should be grouped under the Complex Nursing Interventions group as other ostomy complication codes are included in the Complex Nursing Interventions group.	Complex
M06.9	Rheumatoid Arthritis, unspecified	Not assigned	Commenters recommended assigning to the MS Rehab clinical group with guidance to query the physician for more specific information. Commenters stated that in the HH setting, treatment is designed to deal with mobility issues related to multiple joints.	We disagree with commenters that this particular code should be included in the MS Rehab group. If the patient has multiple joints affected, M06.89, other specified rheumatoid arthritis, multiple sites would be the appropriate code to report.	Not assigned
M54.5	Low Back Pain	Not assigned	While commenters did not provide a specific clinical group, this diagnosis code was recommended by commenters for inclusion in the clinical group variable.	We believe that the case-mix should system avoid, to the fullest extent possible, non-specific or ambiguous ICD–10–CM codes, codes that represent general symptomatic complaints in the elderly population, and codes that lack consensus for clear diagnostic criteria within the medical community. Given the vagueness of this particular code, we question whether this would necessitate the need for home health services absent more information.	Not assigned
M62.81	Muscle weakness, unspecified	None	Commenters recommended assigning to MS Rehab group. Commenters stated that “it is problematic to exclude this code, as there are scenarios in which the patients are seen in the home for muscle weakness when the underlying etiology is unknown, or	We disagree with commenters that this code be assigned to the MS Rehab group. See our more detailed response in this final rule with comment period.	Not assigned

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
			when the original condition, causing the weakness is resolved." Commenters added that M62.81 is identified as a diagnostic code to support medical necessity for home health therapy services by the MACs within their local coverage determinations. Some commenters agreed that this diagnosis lacks specificity, but disagreed that this diagnosis would not be deemed medical necessary. A few commenters stated that when evaluating the assignation of a diagnosis code at the point of care in home health, the coding specialist must consider the available documentation.		
M62.838	Other Muscle Spasm	Not Assigned	Commenters recommended assigning to the MS Rehab group.	We believe that this diagnosis code does not provide sufficient information to substantiate the need for home health services.	Not assigned
M81.0	Age-related osteoporosis w/o current pathological fracture	MS Rehab	Since there is no fracture, commenters suggested moving to MMTA-Other as the services would likely be nursing.	We agree with this commenter's position. Clinically, if this is reported as the principal diagnosis, the primary reason for home health services would be for MMTA.	MMTA-Other
T81.40XA/D/S	Infection following a procedure, unspecified, initial encounter	MMTA-Infect	Commenters stated that the grouper should not include this code as this code lacks specificity and the default code for an infected surgical wound would be T81.49, Infection following a procedure, other surgical site.	We agree with commenters that there are more specific codes that code be reported to indicate an infected surgical wound.	Not assigned
T81.49XA/D/S	Infection following a procedure, subsequent encounter	MMTA-Infect	Commenters recommended that this diagnosis should be assigned to the Wound group as T81.49 is used to	We agree with commenters that ICD-10-CM coding instructions under the three character	Wound

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
			indicate a resolving surgical wound infection when the physician has not documented the depth of the infection.	classification for T81.4, states that these codes indicate a wound abscess following a procedure.	
T81.89XA/D/S	Oher complications of procedures, NEC	MMTA-Other	Commenters recommended assigning to the Wound group.	We agree with commenters that these codes should be assigned to the Wound group as the Coding Clinic, 2014, 1st qtr. States that ICD-10-CM does not provide a specific code to describe a non-healing surgical wound so T81.89XX would be the appropriate code to assign. If a postsurgical wound does not heal due to infection, assign code T81.4XX-, Infection following a procedure. If the wound was closed at one time and is no longer closed, it is coded as disruption. In that case, code T81.3-, Disruption of wound, not elsewhere classified, should be assigned.	Wound
T84.51XX T84.52XX T84.53XX T84.54XX T84.59XX T84.610X T84.611X T84.612X T84.613X T84.614X T84.615X T84.620X T84.631X T84.622X T84.623X	Infection and inflammatory reaction d/t internal joint prosthesis (hip, knee, humerus, radius, femur, tibia, spine, other)	MMTA-Infect	Commenters recommended reassigning to the Wound or MS Rehab. Commenters stated that these patients are usually on long-term antibiotics, often require wound care, and many require removal of their prosthesis and subsequently require therapy.	While we agree that patients with these diagnosis codes reported as principal may require various home health services, we note that these listed diagnoses codes could be present in the absence of an open wound. We consulted with coding experts who state that there are other codes that should be reported in the event of a wound that results from a complication of an internal joint prosthesis including, T8131XD Disruption of external operation (surgical) wound, not elsewhere classified,	MMTA-Infect

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
T84.624X T84.625X T84.63XX T84.69XX T84.7XXX				subsequent encounter We will monitor the resource use associated with these codes to determine if any future changes to coding assignments are warranted.	
T87.41 T87.42 T87.43	Infection of amputation stump, right upper extremity Infection of amputation stump, left upper extremity Infection of amputation stump, right lower extremity	MMTA-Infect	Commenters recommended assigning to the Wound group, stating that these complications of amputations generally require wound care.	It is possible for there to be an infection in the absence of an open wound. If there is an open wound, and the primary reason for home health care is for wound care, we would expect that the code for the wound would be reported as principal. We consulted with coding specialists who state that in the event of a wound at the amputation site, the first listed diagnosis would be dependent on the circumstances of the encounter. There are other codes that could be used to describe a wound at the amputation stump depending on the cause, and documented cause-effect relationship. However, we will continue to examine reported diagnosis codes, and the associated resource use to determine if any future changes to coding assignments are warranted.	MMTA-Infect
Z48.01	Encounter for change or removal of surgical wound dressing	Wound	Commenters stated that this should not be reported as a principal diagnosis for clinical grouping because the clinician would not be in the home just for a dressing change but is likely doing other aftercare and teaching.	Z48.01 is an aftercare code and the coding instructions state that aftercare codes are generally first-listed to explain the specific reason for the encounter. Coding instructions also state that aftercare codes should be used in	Wound

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
				conjunction with other aftercare codes or diagnosis codes to provide better detail on the specifics of an aftercare encounter visit. For example, if the primary reason for the home health period of care is to provide wound care to a surgical wound site following CABG surgery, the HHA could report Z48.01, encounter for change or removal of surgical wound dressing as the principal diagnosis, and Z48.812, Encounter for surgical aftercare on the circulatory system (another aftercare code), to identify the body system requiring aftercare. There is no sequencing guideline provided for these aftercare codes other than they can be reported in conjunction with other aftercare codes. The HHA should report the primary reason for the home health encounter (which in this scenario would be for wound care, even though the clinician can also be providing teaching about the patient's condition).	
Z48.810 Z48.811 Z48.812 Z48.813 Z48.814	Encntr for surgical aftercare following surgery on the sense organs Encntr for surgical aftcr fol surgery on the nervous sys Encntr for surgical aftcr following surgery on the circ sys Encntr for surgical aftcr following surgery on the resp sys Encntr for surgical aftcr following	MMTA-After MMTA-After MMTA-After MMTA-After Not	Commenters recommended that these diagnosis codes be assigned to the Wound group. Commenters stated that all surgical aftercare codes indicate that the patient has had a procedure of some kind, most often with interruption of the skin.	We disagree with commenters that all of these surgical aftercare codes would indicate that the primary reason for home health care would be for wound care. We note that the coding instructions for Z48.81- encounter for aftercare of specific body systems state that these codes are to be used in conjunction with	MMTA-Aftercare

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Commenter Recommended Clinical Group	CMS Response	Finalized Clinical Group
Z48.815 Z48.816 Z48.817	surgery on the teeth or oral cavity Encntr for surgical aftcr following surgery on the GI system Encounter for surgical aftcr following surgery on the GU sys Encntr for surgical aftcr fol surgery on the skin, subcu	assigned MMTA-After MMTA-After MMTA-After		other aftercare codes to fully explain the aftercare encounter. Additionally, if the condition treated should also be coded if still present. Furthermore, we consulted with coding specialists who stated that these encounter for surgical aftercare codes do not specifically indicate the presence of a wound and that there are other codes that would be listed to indicate that the encounter is for wound care.	
Z48.89	Other specified surgical aftercare, NEC	Not assigned	While the commenter did not recommend a specific clinical group, it was suggested that this should be included in the clinical group variable.	We agree with the commenter that this diagnosis code would warrant inclusion for MMTA-Aftercare.	MMTA-Aftercare

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We note that as we were examining the clinical group changes suggested by commenters, we took the opportunity to ensure consistency in the clinical group assignments and have reassigned certain diagnosis codes accordingly. Specifically, we are reassigning the following codes:

TABLE 13: REASSIGNED DIAGNOSIS CODES FOR CLINICAL CONSISTENCY

ICD-10-CM Diagnosis Code	Code Description	Current Clinical Group	Finalized Clinical Group	Rationale
C09.1	Malignant neoplasm of tonsillar pillar (anterior)(posterior)	Not assigned	MMTA-Infect	Other similar codes in the code classification are included in MMTA-Infect (for example M09.0, Malignant neoplasm of tonsillar fossa).
C60.0	Malignant neoplasm of prepuce	Not assigned	MMTA-Infect	Other similar codes in the code classification are included in MMTA-Infect (for example, C60.1, Malignant neoplasm of glans penis).
E03.2	Hypothyroidism d/t meds and other exogenous substances	Not assigned	MMTA-Endo	Other similar codes in the code classification are included in MMTA-Endo (for example, E03.1, Congenital hypothyroidism without goiter).
I21.A9	Other myocardial infarction type	Not assigned	MMTA-Cardiac	Other similar codes in the code classification are included in MMTA-Cardiac (for example, I21.A1, myocardial infarction type 2).
I10	Essential hypertension	MMTA-Other	MMTA-Cardiac	To be clinically consistent with other similar diagnoses in the same diagnosis block of codes (I10-I16, hypertensive diseases) assigned to MMTA-Cardiac.
I80.291	Phlebitis and thrombophlebitis of deep vessels of r low extremity	Not assigned	MMTA-Cardiac	To be clinically consistent with I80.292 (left lower extremity) and I80.293 (bilateral lower extremities) which are included in MMTA-Cardiac.
M05.711	Rheumatoid arthritis w/rheumatoid factor of R shoulder w/o organ system involvement	Not assigned	MS Rehab	To be clinically consistent with M07.712 (L shoulder) which is included in MS Rehab.
T23.162D	Burn of first degree of back of left hand, subsequent encounter	MS Rehab	MMTA-Other	To be clinically consistent with T23.162A and S which are in MMTA-Other.
T84.89XA/D/S	Other specified complication of internal orthopedic prosthetic devices, implants and grafts	MMTA-Other	Wound	We consulted with coding experts who stated this would be reported if there is a wound associated with an internal prosthetic device.
T87.89	Other complications of amputation stump	MMTA-Other	Wound	We consulted with coding experts who stated this would be reported if there is a wound associated with an amputation stump complication.

Comment: Several commenters stated that code M62.81 Muscle Weakness (generalized) should be allowed to be reported as the principal diagnosis used to assign a clinical group. Commenters stated that it is problematic to exclude this code, as there are scenarios in which patients are seen in the home for muscle weakness when the underlying etiology is unknown, or when the original condition, causing the weakness is resolved. Additionally, commenters noted that M62.81 is identified as a diagnostic code to support medical necessity for home health therapy services by the MACs within their local coverage determinations. While commenters agreed that this diagnosis lacks specificity, they stated that they disagree that this diagnosis would not be deemed medically necessary. And finally, commenters stated that when evaluating the assignation of a diagnosis code at the point of care in home health, the coding specialist must consider the available documentation.

Response: As we stated in the CY 2019 HH PPS final rule with comment period (83 FR 56474), M62.81, ''Muscle weakness, generalized'' is a vague code that does not clearly support a rationale for skilled services. Further, the lack of specificity for this code does not support a comprehensive plan of care. We noted that § 409.44(c)(1)(ii) states that ''the patient's clinical record must include documentation describing how the course of therapy treatment for the patient's illness or injury is in accordance with accepted professional standards of clinical practice.'' If there is not an identified cause of muscle weakness, then it would be questionable as to whether the course of therapy treatment would be in accordance with accepted professional standards of clinical practice.

Additionally, it is not without precedent that CMS has been disinclined to include generalized muscle weakness in the home health case-mix. In the 2008 HH PPS final rule, we identified generalized muscle weakness as a nonspecific condition that represents general symptomatic complaints in the elderly population. We stated that inclusion of this code ''would threaten to move the case-mix model away from a foundation of reliable and meaningful diagnosis codes that are appropriate for home care'' (72 FR 49774). The 2008 HH PPS final rule stated that the case-mix system avoid, to the fullest extent possible, non-specific or ambiguous ICD–9–CM codes, codes that represent general symptomatic complaints in the elderly population, and codes that lack consensus for clear diagnostic criteria within the medical community. Expanding upon that assertion, we stated in the CY 2019 final rule with comment period that diagnostic approaches to determining the cause of muscle weakness, polyneuropathy, and other vague conditions, combined with the expanded ICD–10 list, ensure that codes exist which more clearly describe a patient's need for home health (83 FR 56474). With respect to commenter rationale for coding generalized muscle weakness when the underlying etiology is unknown, we believe that by the time a home health referral is made, a more definitive principal diagnosis is warranted in order to justify the need for skilled services and appropriate treatment. Further, if the original condition is resolved, but the resulting muscle weakness persists as a result of the known original diagnosis, we anticipate that a more specific code exists that accounts for why the muscle weakness is on-going, such as muscle wasting or atrophy. As the commenter pointed out, the coding specialist must consider available documentation; however, as we state in the previous discussion regarding symptom codes, we believe it is important for a clinician to investigate the reason for which the referral was made. This may involve calling the referring physician if the original condition is resolved and is not included in the referral documentation.

With respect to commenter reference to the LCD for Physical Therapy in Home Health (L33942), we recognize that M62.81 is identified as a code to support medical necessity. While we are not disputing that services for this diagnosis are considered reasonable and medically necessary, we do not believe it is appropriate to list Muscle weakness, generalized as a principal diagnosis in order to group the home health period. We developed the clinical groupings in large part to clearly identify the need for the home health episode, including the skilled services involved. Allowing use of a vague code that does not clearly denote a treatment plan, would invalidate the transparency we hope to achieve in the home health payment system.

6. Comorbidities

Comment: A commenter questioned why the list of comorbidity codes stopped at the R codes and indicated there should be codes for ''traumas, postoperative complications and the Z codes''. The same commenter questioned why some codes were included in the overall comorbidity list but not all were eligible for a comorbidity adjustment. A commenter requested an explanation the rationale for not including any conditions from the ICD–10–CM chapters with O, P, Q, R, S, T, or Z codes as comorbidity diagnoses as many of these seem appropriate given the significant impact these conditions have on the patient's recovery.

Another commenter questioned why blindness and other low vision codes (Neuro 11) were removed from the comorbidity grouping given their significance in patient treatment and recovery.

Response: As we described in the CY 2018 HH PPS proposed rule (82 FR 35322), we examined multiple approaches for a comorbidity adjustment in the alternate case-mix adjustment methodology and the analyses on these approaches are found in the ''Overview of the Home Health Groupings Model'' technical report found on the HHA Center web page. As we noted in the technical report, secondary diagnosis reporting on the OASIS and home health claims was not as robust as would be expected. As part of that analysis, we also examined claims from prior settings 90 days before the home health start of each home health episode. Again, our analysis showed that diagnosis reporting was not as robust as hypothesized, especially in Part B physician claims where diagnoses reported appeared to be specific to only the condition for which the patient sought care. Furthermore, many secondary diagnosis codes, including those associated with signs, symptoms, and other ill-defined conditions (that is, R-codes) often had an inverse relationship with resource use, meaning the presence of these symptom codes showed less resource use for home health periods of care. Based on the results of these analyses, we proposed and finalized a home health specific comorbidity list for the PDGM comorbidity adjustment, as described in the technical report and in the CY 2018 and CY 2019 HH PPS proposed and final rules. The home health-specific comorbidity list is based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries to develop larger categories of conditions that identified clinically relevant relationships associated with increased resource use. While we are aware of the prevalence of comorbidities, including those associated with symptoms, in the Medicare home health population, we note that the average number of comorbidities in the aggregate becomes the standard within that population for the purpose of payment. As such, the PDGM comorbidity adjustment includes

those comorbid conditions and interaction subgroups that represent more than 0.1 percent of periods and that have at least as high as the median resource use. While there are additional comorbid diagnoses included in the home health-specific list, we note that not all diagnoses are included in a comorbidity subgroup that meets the criteria to receive an adjustment. However, it is expected that HHAs will report those secondary diagnoses that affect care planning and we will continue to evaluate reported secondary diagnoses and interactions between comorbidities to identify their impact on resource costs to determine if any future refinements to this case-mix adjustment variable are warranted.

Regarding the exclusion of diagnosis codes from the ICD–10–CM chapters starting with ''O'', ''P'', or ''Q'', we note that these are diagnosis codes that reflect conditions of pregnancy, childbirth and the puerperium (O00–O9A),certain conditions originating in the perinatal period (P00–P96), and congenital malformations, deformations, and chromosomal abnormalities (Q00–Q99). As such, because we were examining reported diagnoses on Medicare home health claims, these were diagnoses that were not generally reported given the nature of the Medicare patient population. Secondary diagnosis codes identifying signs, symptoms and other ill-defined conditions (R-codes, R00–R99) were examined as part of our analysis for possible inclusion on the comorbidity list, however, these generally did not show any significant correlation on resource use and therefore were not included in the home health specific comorbidity diagnosis list. We note, however, that R00.1, bradycardia, unspecified, is on the comorbidity diagnosis list and is included under the comorbidity subgroup, Heart 10, which does meet the comorbidity adjustment criteria and receives additional payment. The same holds true with the codes that begin with ''S'' or ''T'', representing injury, poisoning, and certain other consequences of external causes (S00–T88) where these codes were not frequently reported as secondary diagnoses on home health claims. Furthermore, we described in detail, in the CY 2018 proposed rule (82 FR 35322), how we developed the home health specific comorbidity diagnosis list, focusing on those chronic conditions that our literature review, and our data analysis, showed to be clinically and statistically significant on their overall impact on home health resource use. Finally, we note that there are diagnosis codes representing blindness and other low-vision conditions on the home health specific comorbidity list (the Neuro 11 subgroup). However, when analyzing CY 2018 home health claims for the CY 2020 comorbidity adjustment, these particular diagnosis codes did not represent more than 0.1 percent of periods or have at least as high as the median resource use and therefore, will not receive a comorbidity adjustment in CY 2020. We take this opportunity to remind commenters that there are diagnosis codes on the home health specific list that will not receive the adjustment in CY 2020, but that does not mean that these would never receive an adjustment. Based on our extensive literature review and previous comments received on what clinically significant secondary diagnoses to include as part of this home health specific list, we believe that if HHAs are reporting these as secondary diagnoses and they have an impact on home health resource use (that is, represent more than 0.1 percent of home health periods of care and have at least as high as the medial resource use), these diagnoses could receive a comorbidity payment adjustment in future years. As such, the comorbidity subgroups that could receive an adjustment in any given year is fluid, depending on the frequency of the reported codes and their impact on resource use. Therefore, we remind commenters of the importance of reporting secondary diagnoses on the home health claim, regardless of whether there is a comorbidity payment adjustment associated with such diagnosis. Likewise, we will continue to examine reported secondary diagnoses on home health claims and their relationship with resource use to determine whether such diagnoses should be included on the home health specific comorbidity list in future years.

Comment: A few commenters noted that there are separate instructions for reporting other/secondary diagnoses on the claim, the OASIS instructions, the CoPs and the interpretive guidelines. These commenters recommended that CMS modify all of these instructions with ICD–10–CM coding guidelines to be consistent with the expectations for reporting of diagnoses.

Response: The ICD–10–CM coding guidelines [13] define ''other'' (additional) diagnoses as ''all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay.'' The OASIS manual instructions [14] state that ''secondary diagnoses are comorbid conditions that exist at the time of the assessment, that are actively addressed in the patient's plan of care, or that have the potential to affect the patient's responsiveness to treatment and rehabilitative prognosis''. The CoPs at § 484.60 state that the home health plan of care must include all ''pertinent diagnoses'' and the accompanying interpretive guidelines state that this means that all ''known diagnoses''. While we recognize that there could be a perceived difference between the various descriptions, we believe that these instructions essentially describe the same thing. Specifically, all of these coding instructions state to include any conditions that exist at the time of home health admission, or that develop during the course of a home health period of care, and that affect patient care planning. That is, diagnoses should be reported that affect or potentially affect patient care (and therefore would be addressed in the home health plan of care), even if such care includes observation and assessment (for actual or potential effects), teaching and training, or direct patient care interventions.

Final Decision: We note that the PDGM was finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and therefore, no structural changes to this case-mix adjustment methodology have been made in this CY 2020 final rule with comment period. Therefore, we are finalizing the implementation of the PDGM for 30-day periods of care beginning on and after January 1, 2020. We are finalizing the coding changes for the clinical group as described in responses to the various diagnosis/clinical group comments. These coding changes will be reflected in the Interactive Grouper Tool posted on the HHA Center web page and also in the downloadable HH PPS grouper [15] that accompanies the publication of this final rule with comment period.

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

[13] ICD–10–CM Official Guidelines for Coding and Reporting FY 2020. *https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf.*

[14] ''Outcome and Assessment Information Set OASIS–D Guidance Manual'', Effective January 1, 2019 *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/draft-OASIS-D-Guidance-Manual-7-2-2018.pdf.*

[15] Home Health PPS Software web page. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/CaseMixGrouperSoftware.html.*

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 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 final rule with comment period (83 FR 56461), we finalized three assumptions about behavior changes 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 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 based on past evidence and as detailed in the CY 2020 proposed and this final rule with comment period.
- *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 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 PDGM, we 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.[16] 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 final rule with comment period for the LUPA thresholds that correspond to the 432 case-mix groups under the PDGM).

For this final rule with comment period, in order to calculate the CY 2020 budget neutral 30-day payment amounts 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.C. 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 $16.6 billion.[17] 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 rule) and in order for Medicare to pay out $16.6 billion in total expenditures in CY 2020 with the application of a 30-day unit of payment under the PDGM. Table 14 includes the 30-day budget-neutral payment amount for CY 2020 both with and without the behavior assumptions based on the most current data available at the time of this final rule with comment period. These amounts vary slightly from those in Table 12 of the proposed rule (84 FR 34616) due to using more up-to-date data. These payment amounts do not include the CY 2020 home health payment update of 1.5 percent.

[16] 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.

[17] The final 2018 analytic file included 6,3388,974 60-day episodes ($18.0 billion in total expenditures as shown on the claim). Of these, 609,947 (9.5 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 rule. We note that of the 609,947 excluded claims, 142,206 were excluded because they were RAPs without a final claim or they were claims with zero payment amounts, resulting in $17.9 billion in total expenditures (as shown on the claim). After removing all 609,947 excluded claims, the 2018 analytic file consisted of 5,779,027 60-day episodes ($16.6 billion in total expenditures ass shown on the claim). 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 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 9,336,898 30-day periods ($16.6 billion in total expenditures that are simulated under the PDGM) drawn from 5,471,454 60-day episodes.

TABLE 14: ESTIMATED 30-DAY BUDGET-NEUTRAL PAYMENT AMOUNTS

Behavior Assumption	30-day Budget Neutral (BN) Standard Amount	Percent Change from No Behavior Assumptions [1]
No Behavior Assumptions	$1,908.18	
LUPA Threshold (1/3 of LUPAs 1-2 visits away from threshold get extra visits and become case-mix adjusted)	$1,872.33	-1.88%
Clinical Group Coding [2] (among available diagnoses, one leading to highest payment clinical grouping classification designated as principal)	$1,786.13	-6.40%
Comorbidity Coding (assigns comorbidity level based on comorbidities appearing on HHA claims and not just OASIS)	$1,903.46	-0.25%
Clinical Group Coding + Comorbidity Coding + LUPA Threshold	$1,748.11	-8.389%

Notes:

[1] Adding all the percent decreases for each behavior assumption results in a total percent decrease of -8.53 percent. However, there is overlap and interactions between the behavior assumptions and when combined, the budget-neutral payment amount results in a -8.389 percent decrease from the payment amount without these assumptions applied.

[2] The clinical group coding assumption has a higher percent decrease (-6.40 percent) in this year's final 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 $1,908.18. 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, would result in the need to decrease the CY 2020 budget-neutral 30-day payment amount to $1,748.11 (an 8.389 percent decrease from $1,908.18). The CY 2020 estimated 30-day budget-neutral payment amount would be slightly less 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 $1,748.11 does not include the 1.5 percent home health legislated payment update for CY 2020. Applying the CY 2020 Wage Index Budget Neutrality Factor and the 1.5 percent home health update as described in section III.E. of this final rule with comment period) would increase the CY 2020 national, standardized 30-day payment amount to $1,785.51. The CY 2020 estimated payment rate of $1,785.51 is approximately 11 percent more than the estimated CY 2020 30-day period cost of $1,608.82, as shown in Table 5 of this final rule with comment period.

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.E.4.b of this final rule with comment period. 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.E.4.d. of this final rule with comment period. 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. We noted in the proposed rule that complete 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 noted that we would analyze preliminary 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 notice and comment rulemaking.

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 solicited comments on the proposed, estimated CY 2020 30-day budget neutral payment amount, as well as any potential issues that may result from taking these behavior assumptions into account when establishing the initial 30-day payment amounts for CY 2020. We did not propose any changes to the behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56461). We received 186 comments on the behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period and the proposed 30-day payment amount for CY 2020 from various stakeholders including home health agencies, industry associations, individual clinicians, and MedPAC. These comments and our responses are summarized in this section of this final rule with comment period.

Comment: Several commenters disagreed with the behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period. Commenters added that given the current regulatory and audit environment, agencies who are coding diagnoses strictly for payment maximization must still keep their focus of care as the primary consideration in coding or their payments will be denied. Commenters went on to state that the home health agency can only code what is already in the medical record and that has been diagnosed by a physician, so there is a limit to which diagnoses may be selected. A commenter stated that CMS is creating an environment wherein agencies will have to modify their coding practices in order to survive. This commenter stated HHAs that would not normally alter their behavior without the reduction will now be forced to.

Response: We continue to believe that the behavior assumptions are reasonable given past experience with changes in provider behavior in response to payment system modifications. We refer readers to the CY 2019 HH PPS final rule with comment period (83 FR 56456), in which we provided examples of observed behavior changes resulting from payment system changes. These examples included the behavior changes resulting from the transition from diagnosis-related groups (DRGs) and the Medicare Severity (MS)-DRGs under the inpatient prospective payment system, and nominal case-mix growth observed from the 2008 changes to the HH PPS case-mix model that resulted in the current 153 home health resource groups. We also believe that there may be additional behavior changes that may result from the change to a new case-mix adjustment methodology that relies more heavily on patient characteristics. For example, given the significant number of ICD–10–CM diagnosis codes that are assigned to a clinical group, HHAs may start reporting diagnoses that were not typically reported on home health claims under the current 153-group model. As we stated in the CY 2020 HH PPS proposed rule (84 FR 34614), we do not support or condone coding practices or the provision of services solely to maximize payment. We fully expect that HHAs would report those diagnoses (both the principal diagnosis and secondary diagnoses) that reflect the primary reason for home health services and those that affect the home health plan of care. This is in accordance with ICD–10–CM coding guidelines, which state to select the principal diagnosis code that reflects the reason for the health care encounter, and to report the additional diagnoses that affect patient care in terms of clinical evaluation, therapeutic treatment, and increased nursing care or monitoring. Furthermore, the specificity and granularity of ICD–10–CM diagnosis codes provide the opportunity for HHAs to improve their diagnosis code reporting to more accurately reflect the reason for home health services and other conditions that affect the home health plan of care. If the supporting documentation from the certifying physician or the acute/post-acute care facility is lacking specificity regarding the patient's diagnoses, the HHA would be expected to query such providers in order to adequately address the patient's home health care needs.

Because one of the variables in the PDGM case-mix adjustment is the clinical grouping, we believe that HHAs would be more comprehensive in their assessment of the patient to identify all diagnoses to determine the individualized patient care needs to be addressed through the home health plan of care. More specific and accurate diagnosis reporting to identify those conditions affecting the home health plan of care and to support the need for services is appropriate. Likewise, the home health Conditions of Participation (CoPs) at § 484.60(a), require that the home health plan of care includes all pertinent diagnoses. HHAs are required to consult the physician if there are any additions or modifications to the plan of care. Therefore, any diagnoses included on the home health plan of care would have to be agreed upon by the physician responsible for the home health plan of care. More accurate and complete reporting of diagnoses is not inappropriate if in accordance with existing regulations and standards of practice. Modification of current coding practices does not mean that HHAs are engaging in inappropriate behavior nor are the coding assumptions meant to encourage any type of negative behavior change. As noted previously, ICD–10–CM diagnosis codes are granular and specific, and provide HHAs a better opportunity to report those codes that reflect the patient's conditions and support the need for home health services. We view improved diagnosis reporting as a positive change that affords HHAs the latitude to fully ''paint the picture'' of their patients receiving home health services.

Comment: Many commenters stated that the behavior assumptions finalized are ''faulty'' with no empirical evidence to support such assumptions or that the behaviors would actually occur. Most often, commenters stated that while changes in coding behavior may occur, the degree to which this may occur and the impact of the occurrence, especially in the first year of the new payment system seems to be exaggerated by CMS. Several commenters stated that their home health agencies do not ''game the system'' and base patients' care plans on what patients need. These commenters believe that they should not be subjected to payment cuts based on Medicare's assumptions, which they believe to be flawed. A few commenters stated that the behavior assumptions penalize those agencies who have been providing care based on patient need and not driven by therapy utilization or other behaviors solely to maximize payment. These commenters indicated that they would not change their current care practices because of this regulation and that they were essentially being punished for doing the right thing all along. They expressed concern over how they would adjust to compensate for an 8 percent reduction in the 30-day payment rate. Other commenters recommended that CMS establish monitoring programs to target providers engaging in in specific behaviors solely for payment purposes rather than ''penalize all providers.'' Several comments indicated that the behavioral assumptions are a punitive action against all home health agencies based on behaviors that have not happened yet and may never happen.

Response: We disagree that the finalized behavior assumptions are without empirical evidence as we have provided multiple examples of previous changes in behavior in response to payment changes, especially as they

relate to coding behavior. In the CY 2020 HH PPS proposed rule (83 FR 56456), we provided examples of such evidence. For the clinical group and comorbidity assumptions when CMS implemented revisions to the home health case-mix system in 2008, subsequent analysis found that behavioral responses unrelated to patient severity caused payments to increase by 4 percent in that year—despite having increased only 1 percent per year, on average, between 2001 and 2007. CMS continued to find nominal increases in case mix unrelated to patient severity in later years and reduced payments by an average of 1.8 percent a year from 2008 through 2017 to account for this trend. We refer commenters to the impact of the coding and comorbidity assumptions in Table 14 of this rule, which is estimated to be 6.4 percent and 0.25 percent respectively, which is similar to other past coding behavior responses described previously and which were associated with the implementation of a new home health payment system.

We also provided additional examples from other Medicare payment systems where coding behaviors led to increases in payment not necessarily related to increases in patient acuity. These include the transition from DRGs to (MS) DRGs; the first year of the IRF PPS; and Maryland's transition to APR DRGs. For the LUPA assumptions, we provided the analysis of the implementation of the HH PPS where the expected rate of LUPAs (16 percent) was much higher than the actual rate of LUPAs (7 percent), indicating that HHAs were providing extra visits to receive a full 60-day episode case-mix adjusted payment amount.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires us to make assumptions about behavior changes that could occur as a result of the change to a 30-day unit of payment and implementation of the PDGM when calculating a 30-day payment amount in a budget-neutral manner. These assumptions are not to account for ''gaming'' of the system as commenters suggest, and we stated as such in the CY 2019 HH PPS proposed rule (83 FR 56455). We clarified that CMS often takes into account anticipated behaviors when making a payment system change. By including behavior change assumptions in the proposed calculation of the 30-day payment amount, as required by statute, we did not intend to imply that HHAs would engage in unethical behavior. Furthermore in the CY 2019 HH PPS final rule with comment period (83 FR 56455), we provided detailed explanation as to why we believe that targeted actions against specific providers who may or may not be engaging in abusive coding patterns would not be effective. Explicitly, we stated that system-wide case-mix levels have risen over time throughout the country, while patient characteristics data indicate little real change in patient severity over that same time. These widespread changes make it challenging to clearly separate agencies into high and low coding change groups. While we do not believe that our overall assumptions are exaggerated, we also recognize commenter concern over the frequency of these behaviors during the first year of the payment changes.

Finally, in the CY 2019 HH PPS final rule with comment period (83 FR 56455), we stated that the behavior assumption adjustment is not meant to be punitive, rather we are required by law to make such assumptions when calculating the 30-day budget-neutral payment amount. MedPAC comments on the CY 2020 HH PPS proposed rule support the finalized behavior assumptions and it states that even with the behavior assumption adjustment, payment would still exceed estimated costs. MedPAC went on to state that most HHAs will be able to absorb the 8.01 percent adjustment.

Comment: A few commenters asserted that such behavior assumptions are not applied to other settings, should not be applied to home care, and applying behavior assumptions absent supporting data is not sound payment policy. Specifically, these commenters mention that CMS, in issuing the Skilled Nursing Facility (SNF) model, refused to make assumptions about provider behavior, stating that it would ''not make any attempt to anticipate or predict provider reactions to the implementation of the proposed [payment model].''

Response: We remind commenters that CMS is required, by statute, to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the PDGM when calculating the 30-day payment amount in a budget neutral manner for CY 2020. Other new payment models, such as the Patient-Driven Payment Model for skilled nursing facilities did not have such a statutory requirement. In compliance with section 1895(b)(3)(A)(iv) of the Act, we believe that we have made reasonable assumptions about what behavior changes to expect with the implementation of the new home health PPS payment structure which are based on previous experience with the HH PPS, as well as other payment systems.

Comment: A commenter stated that there is no evidence to support the clinical group coding assumption. This commenter referenced the analysis of home health improper payments in the CMS 2017 Fee-for-Service Supplemental Improper Payment Data Report [18] stating improper payments due to incorrect coding was zero dollars.

Response: We note that CMS uses the Comprehensive Error Rate Testing (CERT) Program to estimate the Medicare Fee-For-Service (FFS) improper payment rate. The purpose of the CERT Program is to identify payments that should not have been made or payments made in an incorrect amount. Under the CERT Program, the definition of ''incorrect coding'' in the context of the home health improper payments, relates to incorrect HIPPS codes on HH claims, meaning that medical documentation supports different coding than what was billed; that the service was performed by someone other than the billing provider; that the billed service was unbundled; and that a beneficiary was discharged to a site other than the one coded on a claim.[19] For example, an improper payment is made as a result of the HIPPS code reflecting a therapy threshold not supported by entries in the medical record. Therefore, contrary to the commenter's remark, improper home health payments resulting from incorrect coding does not relate to diagnosis codes reported, rather it relates to the reported HIPPS code on home health claims. We note that the most common type of improper payment error in home health is ''insufficient documentation''. This occurs when: There is missing or inadequate medical records; there is a missing certification or recertification or some element of the certification or recertification is missing; there are missing or inadequate orders; there are inconsistent records; there is a missing or inadequate plan of care; or there are multiple universal errors. For home health, ''insufficient documentation'' often means that the home health certification requirements, in entirety or an element, have not been submitted. Therefore, the analysis regarding the home health improper payments is not evidence to negate the clinical coding

[18] 2017 Medicare Fee-for-Service Supplemental Improper Payment Data. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2017-Medicare-FFS-Improper-Payment.pdf.*

[19] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/IntroductiontoComprehensiveErrorRateTesting.pdf.*

assumption. We remind commenters that our position on the coding behavior assumption is that we assume that HHAs will improve their documentation and coding behaviors to more fully account for patient characteristics that impact resource use.

Comment: A commenter supported the comorbidity assumption and stated that prior to this proposal, there was no motivation to code all of the patient's comorbidities and that under the PDGM, HHAs will have the motivation to document all conditions that affect patient care. This commenter stated that this would be a positive change in that it gives a more complete picture of acuity for the patients being cared for by the HHA and would demonstrate that HHAs are caring for very complex, chronically ill patients and perhaps keeping these patients out of more costly care settings.

Response: We agree with this commenter that the availability to report more secondary diagnoses on the home health claim would provide home health agencies with the opportunity to more comprehensively portray all of the comorbidities affecting the home health plan of care. We believe this will benefit HHAs in terms of receiving a payment adjustment to account for the services being provided to address such comorbidities.

Comment: MedPAC noted that the proposed payment reduction of 8.01 percent appears to be consistent with past trends in coding that CMS has reported and supported the behavioral assumptions. MedPAC also commented that the proposed behavior adjustment may not represent all of the behavioral changes that could occur. Specifically, MedPAC suggested that agencies could respond to the new 30-day unit of payment by providing additional visits after an initial 30-day period to trigger an additional 30-day payment, which could result in higher aggregate payments and that CMS should reduce payments to reflect this excess.

Response: We thank MedPAC for their comments. We agree that there may be other behavior changes that could result from a new case-mix system and a change in the unit of payment, including the behavior MedPAC describes. However, we are not adding a prospective adjustment to account for this additional potential behavior change for CY 2020 as we believe that the behavior changes finalized in the CY 2019 final rule with comment period are the ones best supported based on our experience with changes to payment systems for home health and other provider types. As required by the statute, we will analyze data for CYs 2020 through 2026 to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. This means, we would examine all behavior changes and not just those assumed to determine their impact on overall expenditures. CMS, at a time and in a manner appropriate, is required to determine whether the 30-day payment amounts needs to be increased or decreased in response to actual observed behavior change. We interpret actual observed behavior change to encompass both behavior changes that were previously outlined, as assumed by CMS when calculating 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.

Comment: Several commenters requested CMS provide expected total aggregated budget neutral HH PPS expenditures for future years and requested to further understand how the cases dropped from PDGM would be accounted for in the budget neutrality calculations. Another commenter stated that all existing work papers on the PDGM behavior adjustment by any party within CMS, including the Office of the Actuary, should be made readily available to the public through the CMS website. These comments express significant concerns that the dropped claims violate the *Jimmo vs. Sebelius* settlement agreement by excluding them from the analysis and not recognizing the patient needs in PDGM. Another commenter recommends that CMS should publish for public notice and comment a full description of its behavior adjustment calculation, including all the specific data used in the assessment along with the complete calculation methodology. A commenter expressed concerns that CMS is not considering the requirements of the Regulatory Flexibility Act or the Small Business Regulatory Enforcement Fairness Act, which limits the impact on small businesses. This commenter stated that many home health agencies are considered ''small business'' and should be afforded targeted oversight efforts rather than apply all claims to the behavioral assumption analysis. The commenter recommended that CMS consider alternatives to the behavioral adjustment that would take into account any oversight to prevent up coding or unnecessary utilization increased to offset the behavioral adjustment.

Response: We believe that it would be difficult to accurately predict total aggregate budget neutral HH PPS expenditures for future years because we cannot anticipate future year home health rate updates, which vary from year to year. Furthermore, we cannot anticipate any future legislative action that would require a set home health rate update for any given year. As such, we do not believe that providing this type of data would produce meaningful results for providers' analytic purposes. However, with the proposed and this final rule with comment period, we released the ''Home Health Claims—OASIS'' Limited Data Set (LDS) file, which contains information on the utilization of the Medicare Home Health benefit on the CMS website.[20] This LDS file is meant to support HHAs in evaluating the effects of the PDGM and provides detailed information for HHAs. Therefore, we believe that we have provided sufficient publically available information for HHAs to utilize so they can fully understand the effects of the PDGM.

We remind commenters that we did provide a detailed explanation as to how we calculated the behavior adjustment in the CY 2020 proposed rule (84 FR 34615). For this final rule with comment period, we used a 2018 analytic file that included 6,388,974 60-day episodes ($18 billion in total expenditures); however 9.5 percent of claims were excluded because they could not be linked to an OASIS assessment, or were RAPs without a final claim, or they were claims with zero payment amounts. After these and other exclusions, the resulting 2018 analytic file represented 5,471,454 60-day episodes and $16.6 billion in total expenditures. We do not agree that these excluded claims would be useful for inclusion of the behavior assumption adjustment, nor do we see any relationship between standard data cleaning procedures and the *Jimmo* v. *Sebelius* settlement, which addresses Medicare coverage of certain types of maintenance therapy for certain Medicare providers, and does not reflect any behavioral analyses. Furthermore, we believe the PDGM captures patient characteristics more closely associated with complex care needs of the chronically ill as we have demonstrated in our analysis of the PDGM (and previously, the HHGM). We also disagree that this rule does not consider the requirements of the Regulatory Flexibility Act or the Small Business Regulatory Enforcement Fairness Act, which limits the impact on small

[20] Home Health Prospective Payment System (HH PPS) Limited Data Set (LDS) web page. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/Home_Health_PPS_LDS.html.*

businesses. In fact, we are required to consider the impact of these policies as we do in the Regulatory Impact Analysis section of the proposed and final rules. Additionally, we refer commenters to Table 36 in the CY 2020 proposed rule that shows the CY 2020 estimated HHA impacts by facility type and area of the country. Even with the 8.01 percent adjustment based on assumed behavior changes, we note that smaller providers would have an estimated impact of a +2.1 percent increase in payments as a result of the PDGM and an estimated overall impact of +3.6 percent as a result of the proposed payment policies in CY 2020. Finally, as noted throughout this rule, CMS is required to reconcile the difference between assumed and observed behavior changes; that is, we are required to examine the data beginning in CY 2020 through CY 2026 to determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures to determine whether any temporary adjustments for retrospective behavior or any permanent adjustments on a prospective basis are warranted to offset such increases or decreases.

Comment: A commenter recommended that CMS should factor the impact of decreased Medicare payments due to home health agency closures as part of the budget neutrality analysis. This commenter stated that evidence exists to support that a change to a new payment system will lead to agency closures and provided the example of the change from cost reimbursement payment system to the Interim Payment System and then to the Home Health Prospective Payment System, which resulted in a 30 percent reduction in the number of home health agencies. The commenter stated that the CY 2020 PDGM Agency Level Impacts file posted with the CY 2020 proposed rule is misleading because it gives an estimated PDGM revenue that does not include the adjustment due to the behavioral assumptions.

Response: We agree with commenters that there have been notable changes in the provision of home health services since the 1980s. MedPAC has provided a detailed description of the use and growth of the home health benefit and has shown how the benefit has varied substantially because of changes in coverage and payment policy in its reports.[21] We remind commenters that implementation of the inpatient hospital PPS in 1983 led to increased use of home health services as hospital lengths of stay decreased. As a result, the number of home health agencies (HHAs), users, and services expanded rapidly in the early 1990s. As the rates of use and the duration of home health episodes increased, there was concern that the benefit was serving more as a long-term care benefit.[22] The trends of the early 1990s prompted increased program integrity actions, refinements of coverage standards, temporary spending caps through an interim payment system (IPS), and the eventual replacement of the cost-based payment system with a prospective payment system in 2000. We agree that the implementation of the IPS resulted in a decrease in the number of HHAs. However, after the HH PPS was implemented, home health service use and agency supply rebounded at a rapid pace. Between 2001 and 2017, the number of home health episodes rose from 3.9 million to 6.3 million.[23] In 2017, the number of HHAs was 11,844—higher than the level of supply during the 1990s. Almost all the new agencies since implementation of the PPS have been for-profit providers. We also note that in the CY 2014 HH PPS final rule (78 FR 72282), commenters expressed similar concerns that HHAs would be forced to close in response to the rebasing adjustment to the 60-day national, standardized episode payment amount, required by section 3131(a) of the Patient Protection and Affordable Care Act (PPACA). In the CY 2014 HH PPS final rule, we finalized a 2.8 percent reduction to the national, standardized 60-day episode payment rate in each year beginning in CY 2014 through CY 2017. However, MedPAC has reported that even with these rebasing reductions, HHAs were able to adapt and there was no evidence of large-scale HHA closures or issues with access to care. In fact, MedPAC reported that changes in average payment per full episode (defined as episodes of more than four visits) underscored the limited impact of the PPACA rebasing policy that was implemented in 2014. Average payment per episode increased in the first three years of rebasing and the average payment per episode in 2016, the third year of rebasing, was 3.1 percent higher than the average payment per episode in 2013, before rebasing was implemented.[24] Therefore, we do not believe there will be large-scale HHA closures or issues with access to care as a result of the implementation of the PDGM, given past experience of HHAs adapting to payment system changes.

While we recognize that there can be a shift in provider practice patterns in response to payment changes, we believe that the PDGM puts patient characteristics and other pertinent clinical information at the forefront in adjusting home health payments to account for increases in resource use. We believe this is an improvement over other significant, past case-mix adjustment and payment changes because of the primary focus on patient characteristics that affect resource utilization. However, we are also aware that the transition to a 30-day unit of payment and implementation of a new case-mix system, the first significant payment changes to the HH PPS in almost 20 years, warrants modifications to HHA billing practices, software systems, and staff education. As we have stated since we finalized the PDGM in the CY 2019 final rule with comment period, we will continue to monitor the provision of home health services, including any changes in the composition of the disciplines providing such services, overall home health payments, and any effects on HHAs to determine if any unintended consequences result from the change in the case-mix adjustment methodology and the 30-day unit of payment that may warrant refinements in future rulemaking.

Comment: Most commenters expressed concern about the impact of the proposed 8.01 percent reduction in payment based on assumed behavior changes that HHAs may make in response to the change in the case-mix adjustment methodology and the change to a 30-day unit of payment. Commenters stated that this reduction would be one of the most significant reductions taken in any new or existing Medicare payment systems to date and would result in negative financial consequences, especially for smaller, rural HHAs that may not be able to make the changes necessary to adapt to the PDGM immediately upon implementation.

Response: We note that the overall impact on the estimated aggregate expenditures resulting from the PDGM and the 30-day unit of payment is zero

[21] MedPAC report, ''Home Care Services'', March 2019. *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch9_sec.pdf?sfvrsn=0.*

[22] Government Accountability Office. 1996. Medicare: Home health utilization expands while program controls deteriorate. GAO/HEHS–96–16. Washington, DC: GAO.

[23] MedPAC report, ''Home Care Services'', March 2019. *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch9_sec.pdf?sfvrsn=0.*

[24] MedPAC Report, Home Care Services'', chapter 9, March 2018. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch9_sec.pdf?sfvrsn=0.*

given the statutory requirement that these changes are implemented in a budget-neutral manner. We appreciate commenter concerns regarding the impact of these assumptions on smaller and rural HHAs. We refer to Table 36 in the CY 2020 HH PPS proposed rule (84 FR 34706), which shows that the impact of the PDGM and the 30-day unit of payment (with behavior assumptions) on rural providers would be 3.7 percent and the impact on smaller providers (less than 100 episodes) would be 2.1 percent. Therefore, we believe that rural and smaller HHAs would recognize an increase in overall payments under the PDGM and the 30-day unit of payment.

We also remind commenters that even with the behavior assumption adjustment of 8.389 percent, the CY 2020 30-day payment rate of $1,785.51 (including the wage index standardization factor and the CY 2020 rate update) would be approximately 11 percent higher than the estimated, CY 2020 30-day period cost of $1,608.82. Additionally, in its comments on the proposed rule, MedPAC states that the analysis of payments and costs in the proposed rule suggests that payments will be more than adequate in 2020. However, we will continue to monitor the effect of the payment changes, including the impacts on smaller and rural providers to mitigate any potential unintended consequences. Moreover, we are required to examine the data beginning in CY 2020 through CY 2026 to determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures to determine whether any temporary adjustments for retrospective behavior or any permanent adjustments on a prospective basis are warranted to offset such increases or decreases.

Comment: Many commenters stated that the magnitude of the 8.01 percent reduction to the home health 30-day payment rate has the potential to create negative consequences for providers transitioning to a new case-mix adjustment methodology and a change in the unit of payment. Several commenters mentioned the provider burden associated with other existing and new requirements, including HHVBP and the resumption of the Review Choice Demonstration and stated that there are too many changes occurring simultaneously and that many HHAs, especially smaller and rural providers, could not incur the costs of all of these changes all at once. Several commenters stated they recognize the statutory requirement to make such behavior assumptions when calculating the budget-neutral 30-day payment rate, but requested that CMS phase-in the behavior assumption reduction over a period of three years, rather than all at one time. Several commenters recognize the phase-out of the rural add-on is based on the Bipartisan Budget Act of 2018 with no latitude to revise the proposal, however, they suggest CMS takes this into consideration in relation to the 8.01 behavioral adjustment. Some commenters indicate the phase-out of the rural add-on payment, coupled with other payment system changes, would be difficult for rural HHAs to fiscally manage. Other commenters stated the assumption that 100 percent of providers will change coding practices and make such changes 100 percent of the time, without sufficient data, is an overestimation and suggested that reduction percentage be halved, as this is a more realistic assumption about the frequency of such behavior changes.

Response: We appreciate commenter concerns about the potential impact of the behavior assumption adjustment. We recognize that transitioning to the first significant HH PPS payment system change in almost 20 years requires a considerable amount of system changes, staff education, and modification of current billing processes. We are also cognizant that there have been recent changes to the home health CoPs, as well as a resumption of the Review Choice Demonstration, and continuation of the HHVBP for some select states. We also understand concerns by rural HHAs as to the impact of the phase-out of the rural add-on payment coupled with other changes that may challenge their fiscal management.

We continue to believe that the behavior assumptions are valid ones and supported by evidence as described in the CY 2019 final rule with comment period and the CY 2020 proposed rule. However, given the scale of the payment system changes, we agree that it might take HHAs more time before they fully implement the behavior assumed by CMS. As we noted in response to comments in the CY 2019 HH PPS final rule with comment (83 FR 56456), in the FY 2008 IPPS final rule, CMS estimated that a total adjustment of 4.8 percent would be necessary to maintain budget neutrality for the transition to the MS–DRGs (72 FR 47178). However, examining subsequent analysis of claims data for FYs 2008 and 2009, our actuaries determined that the implementation of the MS–DRG system resulted in a 2.5 percent change in documentation and coding (about half of the estimated 4.8 percent change expected) in the first year of the MS–DRGs and a 5.4 percent change in documentation and coding in the second year of the MS–DRGs. Taking into consideration the example above and the transition to the new PDGM payment system in combination with other ongoing or new home health requirements, we believe it is reasonable to apply the three previously outlined behavior change assumptions to only half of the 30-day periods in our analytic file (randomly selected). Note that since payment is made for 30-day periods, it is more accurate to apply the behavior assumptions to half the 30-day periods than to assume the magnitude of the behaviors would be halved. Therefore, taking this approach means that the resulting adjustment to the 30-day payment amount needed to maintain budget neutrality, as required by law, is an adjustment of −4.36 percent. This means that the CY 2020 30-day budget-neutral payment amount will be $1,824.99 (not including the wage index standardization factor and the 1.5 percent home health rate update for CY 2020).

We remind commenters that after implementation of the 30-day unit of payment and the PDGM, CMS is required by law to annually analyze data from CYs 2020–2026 to determine the impact of the difference between assumed behavior changes and actual behavior changes to determine if any temporary or permanent payment adjustments to the 30-day payment amount are needed to offset for such increases or decreases in estimated aggregate expenditures. Therefore, if CMS underestimates the amount of the reductions to the 30-day payment rate necessary to offset behavior changes and maintain budget neutrality for CY 2020, larger adjustments to the 30-day payment amount would be required in the future, pursuant to section 1895(b)(3)(D) of the Act, to ensure budget neutrality with respect to estimated expenditures for CY 2020. Likewise, if CMS overestimates the reductions, we are required to make the appropriate payment adjustments accordingly, as described previously. The law also requires that any permanent or temporary payment adjustment would be proposed through rulemaking. We will review data from CY 2020 to inform next year's rulemaking to determine if any change to the behavior assumption adjustment percentage should be proposed in CY 2021 (for example, if the full 8.389 percent reduction should be proposed in CY 2021 based on actual, observed data from CY 2020). While we are applying all three assumptions for establishing a 30-day payment rate, we are changing our assumption regarding

the frequency with which those behaviors would occur in the first year of implementation.

Final Decision: Based on the comments received and reconsideration as to frequency of the assumed behaviors during the first year of the transition to a new unit of payment and case-mix adjustment methodology, we are finalizing a −4.36 percent behavior change assumptions adjustment in order to calculate the 30-day payment rate in a budget-neutral manner for CY 2020. This adjustment will be made using the three behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

The finalized 30-day budget-neutral payment amount with the −4.36 percent behavioral assumption adjustment will be $1,824.99 and the CY 2020 30-day payment rate, with the wage-index budget neutrality factor and the home health payment update of 1.5 percent, will be $1,864.03 with a fixed-dollar loss ratio of 0.56. Section III.E. of this final rule with comment period describes the CY 2020 home health payment rate update and section III.F. describes the payments for high-cost outliers and the fixed-dollar loss ratio for the CY 2020 HH PPS.

Finally, we also wish to remind stakeholders again that CMS will provide, upon request, a Home Health Claims-OASIS LDS file to accompany the CY 2020 final rule with comment period 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 CMS Limited Data Set (LDS) Files website. Additionally, we have posted the CY 2020 provider-level impacts and an updated Interactive Grouper Tool on the HHA Center web page and the PDGM web page 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.[25]

C. 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. The CY 2020 HH PPS proposed rule (84 FR 34617), outlined the implementation of the PDGM and a change in the unit of home health payment to 30-day periods of care. As such, we are recalibrating the CY 2020 case-mix weights for 30-day periods of care using the PDGM methodology. 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. We did not propose to separately recalibrate the case-mix weights for those 60-day episodes that span the January 1, 2020 implementation date, rather we proposed, that these 60-day episodes would be paid the national, standardized 60-day episode payment amount and would be case-mix adjusted using the CY 2019 case-mix weights as listed in Table 6 in the CY 2019 HH PPS final rule with comment period (83 FR 56422) and posted on the HHA Center web page. With the implementation of a new case-mix adjustment methodology and a move to a 30-day unit of payment, we believe this approach will 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 proposed 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 solicited comments on the proposed payment for 60-day episodes of care that span the January 1, 2020 implementation date of the PDGM and the change to a 30-day unit of payment. We received a comment from an industry association and this comment and our response is summarized in this section of this final rule with comment period.

Comment: A commenter did not agree with our proposal to not recalculate the of case-mix weights for 60-day episodes that span implementation of the PDGM and the change to a 30-day unit of payment given that the national, standardized 60-day episode payment rate is being updated for CY 2020. This commenter stated that all variables that affect payment in CY 2020 should be updated for 2020.

Response: We note that we are recalibrating the case-mix weights for 30-day periods of care beginning in CY 2020 in accordance with our policy to annually recalibrate the HH PPS case-mix weights. We note that any recalibration to the case-mix weights for those 60-day episodes that span the January 1, 2020 implementation date of the new case-mix system and the change to a 30-day unit of payment would be very similar to the CY 2019 case-mix weights. We remind commenters that we did propose to update the national, standardized 60-day episode payment amount for CY 2020, which does result in an increased base rate for these episodes of care. We continue to believe that this approach to the case-mix weights for those 60-day episodes that span into CY 2020 is less burdensome for HHAs who are transitioning to a new case-mix methodology and a 30-day unit of payment.

Final Decision: We are finalizing as proposed that 60-day episodes spanning the January 1, 2020 implementation date of the PDGM and the change to a 30-day unit of payment will be paid the CY 2020 national, standardized 60-day episode payment amount of $3,220.79 (see Table 17), and will be case-mix adjusted using the CY 2019 case-mix weights as listed in the CY 2019 HH PPS final rule with comment period (83 FR 56422) and posted on the HHA Center web page.[26] Additionally, for those 60-day episodes that end after January 1, 2020, but where there is a continued need for home health services, any subsequent periods of care will be paid the CY 2020 national, standardized 30-day period payment amount (as shown in section III.E of this final rule with comment period) with the appropriate CY 2020 PDGM case-mix weight applied.

D. CY 2020 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

1. 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

[25] Home Health Agency (HHA) Center web page. *https://www.cms.gov/center/provider-type/home-health-agency-hha-center.html.*

[26] Home Health Agency web page. *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.*

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 with comment period (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 July 31, 2019) linked to OASIS assessment data for this rule. The 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 16. 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.

2. 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 with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient characteristics (principal diagnosis, functional level, comorbid conditions, admission source and timing). The PDGM case-mix methodology results in 432 unique case-mix groups called Home Health Resource Groups (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 July 31, 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 final rule with comment period:

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 15 shows the coefficients of the payment regression used to generate the weights, and the

coefficients divided by average resource use.

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TABLE 15 – COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE FOR PDGM PAYMENT GROUP

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
MMTA - Other - Medium Functional	$214.31	1.0%	0.1315
MMTA - Other - High Functional	$372.40	0.9%	0.2284
MMTA - Surgical Aftercare - Low Functional	-$162.07	1.2%	-0.0994
MMTA - Surgical Aftercare - Medium Functional	$84.32	1.1%	0.0517
MMTA - Surgical Aftercare - High Functional	$338.61	1.1%	0.2077
MMTA - Cardiac and Circulatory - Low Functional	-$73.31	8.0%	-0.0450
MMTA - Cardiac and Circulatory - Medium Functional	$169.91	7.6%	0.1042
MMTA - Cardiac and Circulatory - High Functional	$349.95	6.3%	0.2147
MMTA - Endocrine - Low Functional	$137.79	2.5%	0.0856
MMTA - Endocrine - Medium Functional	$416.82	2.6%	0.2588
MMTA - Endocrine - High Functional	$603.96	2.0%	0.3750
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$90.97	1.5%	-0.0565
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$158.28	1.2%	0.0983
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$298.14	1.4%	0.1851
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$37.90	1.3%	-0.0235
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$164.86	1.3%	0.1024
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$347.73	1.2%	0.2159
MMTA - Respiratory - Low Functional	-$78.94	2.8%	-0.0490
MMTA - Respiratory - Medium Functional	$142.86	2.8%	0.0887
MMTA - Respiratory - High Functional	$316.55	2.7%	0.1966
Behavioral Health - Low Functional	-$135.26	1.1%	-0.0840
Behavioral Health - Medium Functional	$126.20	1.0%	0.0784
Behavioral Health - High Functional	$269.59	1.0%	0.1674
Complex - Low Functional	-$95.55	1.5%	-0.0593
Complex - Medium Functional	$215.95	1.4%	0.1341
Complex - High Functional	$316.11	1.5%	0.1963
MS Rehab - Low Functional	$111.08	6.4%	0.0690
MS Rehab - Medium Functional	$288.50	6.3%	0.1791
MS Rehab - High Functional	$538.06	6.1%	0.3341
Neuro - Low Functional	$290.55	3.5%	0.1804
Neuro - Medium Functional	$547.74	3.3%	0.3401
Neuro - High Functional	$712.48	3.4%	0.4424
Wound - Low Functional	$377.59	4.2%	0.2345
Wound - Medium Functional	$609.93	3.8%	0.3787
Wound - High Functional	$810.36	3.9%	0.5032

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Admission Source with Timing (Community Early is excluded)			
Community – Late	-$653.92	61.4%	-0.4061
Institutional – Early	$290.05	18.5%	0.1801
Institutional – Late	$66.67	6.8%	0.0414
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$81.70	35.5%	0.0507
Comorbidity Adjustment - Has at least one interaction from interaction list	$237.33	8.1%	0.1474
Constant	$1,630.32		1.0124
Average Resource Use	$1,610.42		
Number of 30-day Periods	8,649,687		
Adjusted R-Squared	0.3087		

Table 16 presents the HIPPS code, the LUPA threshold, and the case-mix weight for each Home Health Resource Group (HHRG) in the regression model for CY 2020.

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TABLE 16–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	1.1798
1FC21	Behavioral Health – High	Early - Community	1	4	1.2305
1FC31	Behavioral Health – High	Early - Community	2	4	1.3271
2FC11	Behavioral Health – High	Early - Institutional	0	4	1.3599
2FC21	Behavioral Health – High	Early - Institutional	1	4	1.4106
2FC31	Behavioral Health – High	Early - Institutional	2	4	1.5072
3FC11	Behavioral Health – High	Late - Community	0	2	0.7737
3FC21	Behavioral Health – High	Late - Community	1	2	0.8244
3FC31	Behavioral Health – High	Late - Community	2	3	0.9211
4FC11	Behavioral Health – High	Late - Institutional	0	3	1.2212
4FC21	Behavioral Health - High	Late - Institutional	1	3	1.2719
4FC31	Behavioral Health - High	Late - Institutional	2	3	1.3685
1FA11	Behavioral Health - Low	Early - Community	0	3	0.9284
1FA21	Behavioral Health - Low	Early - Community	1	4	0.9791
1FA31	Behavioral Health - Low	Early - Community	2	3	1.0757
2FA11	Behavioral Health - Low	Early - Institutional	0	3	1.1085
2FA21	Behavioral Health - Low	Early - Institutional	1	3	1.1592
2FA31	Behavioral Health - Low	Early - Institutional	2	3	1.2558

3FA11	Behavioral Health - Low	Late - Community	0	2	0.5223
3FA21	Behavioral Health - Low	Late - Community	1	2	0.5730
3FA31	Behavioral Health - Low	Late - Community	2	2	0.6697
4FA11	Behavioral Health - Low	Late - Institutional	0	2	0.9698
4FA21	Behavioral Health - Low	Late - Institutional	1	2	1.0205
4FA31	Behavioral Health - Low	Late - Institutional	2	2	1.1171
1FB11	Behavioral Health - Medium	Early - Community	0	4	1.0907
1FB21	Behavioral Health - Medium	Early - Community	1	4	1.1414
1FB31	Behavioral Health - Medium	Early - Community	2	5	1.2381
2FB11	Behavioral Health - Medium	Early - Institutional	0	4	1.2708
2FB21	Behavioral Health - Medium	Early - Institutional	1	4	1.3216
2FB31	Behavioral Health - Medium	Early - Institutional	2	3	1.4182
3FB11	Behavioral Health - Medium	Late - Community	0	2	0.6847
3FB21	Behavioral Health - Medium	Late - Community	1	2	0.7354
3FB31	Behavioral Health - Medium	Late - Community	2	2	0.8320
4FB11	Behavioral Health - Medium	Late - Institutional	0	3	1.1321
4FB21	Behavioral Health - Medium	Late - Institutional	1	3	1.1828
4FB31	Behavioral Health - Medium	Late - Institutional	2	3	1.2795
1DC11	Complex - High	Early - Community	0	3	1.2086
1DC21	Complex - High	Early - Community	1	2	1.2594
1DC31	Complex - High	Early - Community	2	2	1.3560
2DC11	Complex - High	Early - Institutional	0	4	1.3888
2DC21	Complex - High	Early - Institutional	1	4	1.4395
2DC31	Complex - High	Early - Institutional	2	4	1.5361
3DC11	Complex - High	Late - Community	0	2	0.8026
3DC21	Complex - High	Late - Community	1	2	0.8533
3DC31	Complex - High	Late - Community	2	2	0.9500
4DC11	Complex - High	Late - Institutional	0	3	1.2500
4DC21	Complex - High	Late - Institutional	1	3	1.3008
4DC31	Complex - High	Late - Institutional	2	3	1.3974
1DA11	Complex - Low	Early - Community	0	3	0.9530
1DA21	Complex - Low	Early - Community	1	3	1.0037
1DA31	Complex - Low	Early - Community	2	2	1.1004
2DA11	Complex - Low	Early - Institutional	0	3	1.1331
2DA21	Complex - Low	Early - Institutional	1	3	1.1839
2DA31	Complex - Low	Early - Institutional	2	3	1.2805
3DA11	Complex - Low	Late - Community	0	2	0.5470
3DA21	Complex - Low	Late - Community	1	2	0.5977
3DA31	Complex - Low	Late - Community	2	2	0.6943
4DA11	Complex - Low	Late - Institutional	0	2	0.9944
4DA21	Complex - Low	Late - Institutional	1	2	1.0452

4DA31	Complex - Low	Late - Institutional	2	2	1.1418
1DB11	Complex - Medium	Early - Community	0	3	1.1464
1DB21	Complex - Medium	Early - Community	1	3	1.1972
1DB31	Complex - Medium	Early - Community	2	2	1.2938
2DB11	Complex - Medium	Early - Institutional	0	4	1.3266
2DB21	Complex - Medium	Early - Institutional	1	4	1.3773
2DB31	Complex - Medium	Early - Institutional	2	4	1.4739
3DB11	Complex - Medium	Late - Community	0	2	0.7404
3DB21	Complex - Medium	Late - Community	1	2	0.7911
3DB31	Complex - Medium	Late - Community	2	2	0.8878
4DB11	Complex - Medium	Late - Institutional	0	3	1.1878
4DB21	Complex - Medium	Late - Institutional	1	3	1.2386
4DB31	Complex - Medium	Late - Institutional	2	3	1.3352
1HC11	MMTA - Cardiac - High	Early - Community	0	5	1.2297
1HC21	MMTA - Cardiac - High	Early - Community	1	5	1.2804
1HC31	MMTA - Cardiac - High	Early - Community	2	4	1.3770
2HC11	MMTA - Cardiac - High	Early - Institutional	0	4	1.4098
2HC21	MMTA - Cardiac - High	Early - Institutional	1	4	1.4605
2HC31	MMTA - Cardiac - High	Early - Institutional	2	5	1.5571
3HC11	MMTA - Cardiac - High	Late - Community	0	2	0.8236
3HC21	MMTA - Cardiac - High	Late - Community	1	2	0.8743
3HC31	MMTA - Cardiac - High	Late - Community	2	3	0.9710
4HC11	MMTA - Cardiac - High	Late - Institutional	0	4	1.2711
4HC21	MMTA - Cardiac - High	Late - Institutional	1	3	1.3218
4HC31	MMTA - Cardiac - High	Late - Institutional	2	4	1.4184
1HA11	MMTA - Cardiac - Low	Early - Community	0	4	0.9668
1HA21	MMTA - Cardiac - Low	Early - Community	1	4	1.0176
1HA31	MMTA - Cardiac - Low	Early - Community	2	4	1.1142
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	4	1.1469
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	4	1.1977
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	4	1.2943
3HA11	MMTA - Cardiac - Low	Late - Community	0	2	0.5608
3HA21	MMTA - Cardiac - Low	Late - Community	1	2	0.6115
3HA31	MMTA - Cardiac - Low	Late - Community	2	2	0.7081
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	3	1.0082
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	3	1.0590
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	3	1.1556
1HB11	MMTA - Cardiac - Medium	Early - Community	0	5	1.1179
1HB21	MMTA - Cardiac - Medium	Early - Community	1	5	1.1686
1HB31	MMTA - Cardiac - Medium	Early - Community	2	5	1.2652
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	5	1.2980

2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	4	1.3487
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	5	1.4453
3HB11	MMTA - Cardiac - Medium	Late - Community	0	2	0.7118
3HB21	MMTA - Cardiac - Medium	Late - Community	1	2	0.7625
3HB31	MMTA - Cardiac - Medium	Late - Community	2	3	0.8592
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	3	1.1593
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	3	1.2100
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	4	1.3066
1IC11	MMTA - Endocrine - High	Early - Community	0	5	1.3874
1IC21	MMTA - Endocrine - High	Early - Community	1	5	1.4381
1IC31	MMTA - Endocrine - High	Early - Community	2	5	1.5348
2IC11	MMTA - Endocrine - High	Early - Institutional	0	4	1.5675
2IC21	MMTA - Endocrine - High	Early - Institutional	1	4	1.6182
2IC31	MMTA - Endocrine - High	Early - Institutional	2	4	1.7149
3IC11	MMTA - Endocrine - High	Late - Community	0	3	0.9813
3IC21	MMTA - Endocrine - High	Late - Community	1	3	1.0321
3IC31	MMTA - Endocrine - High	Late - Community	2	3	1.1287
4IC11	MMTA - Endocrine - High	Late - Institutional	0	4	1.4288
4IC21	MMTA - Endocrine - High	Late - Institutional	1	3	1.4795
4IC31	MMTA - Endocrine - High	Late - Institutional	2	3	1.5762
1IA11	MMTA - Endocrine - Low	Early - Community	0	4	1.0979
1IA21	MMTA - Endocrine - Low	Early - Community	1	4	1.1486
1IA31	MMTA - Endocrine - Low	Early - Community	2	4	1.2453
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	3	1.2780
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	3	1.3288
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	4	1.4254
3IA11	MMTA - Endocrine - Low	Late - Community	0	2	0.6919
3IA21	MMTA - Endocrine - Low	Late - Community	1	2	0.7426
3IA31	MMTA - Endocrine - Low	Late - Community	2	3	0.8392
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	3	1.1393
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	3	1.1900
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	3	1.2867
1IB11	MMTA - Endocrine -Medium	Early - Community	0	5	1.2712
1IB21	MMTA - Endocrine - Medium	Early - Community	1	5	1.3219
1IB31	MMTA - Endocrine - Medium	Early - Community	2	4	1.4186
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	5	1.4513
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	4	1.5020
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	5	1.5987
3IB11	MMTA - Endocrine - Medium	Late - Community	0	3	0.8651
3IB21	MMTA - Endocrine - Medium	Late - Community	1	3	0.9159
3IB31	MMTA - Endocrine - Medium	Late - Community	2	3	1.0125

4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	3	1.3126
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	3	1.3633
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	4	1.4600
1JC11	MMTA - GI/GU - High	Early - Community	0	4	1.1975
1JC21	MMTA - GI/GU - High	Early - Community	1	3	1.2482
1JC31	MMTA - GI/GU - High	Early - Community	2	3	1.3449
2JC11	MMTA - GI/GU - High	Early - Institutional	0	4	1.3776
2JC21	MMTA - GI/GU - High	Early - Institutional	1	4	1.4283
2JC31	MMTA - GI/GU - High	Early - Institutional	2	4	1.5250
3JC11	MMTA - GI/GU - High	Late - Community	0	2	0.7914
3JC21	MMTA - GI/GU - High	Late - Community	1	2	0.8422
3JC31	MMTA - GI/GU - High	Late - Community	2	2	0.9388
4JC11	MMTA - GI/GU - High	Late - Institutional	0	3	1.2389
4JC21	MMTA - GI/GU - High	Late - Institutional	1	3	1.2896
4JC31	MMTA - GI/GU - High	Late - Institutional	2	4	1.3863
1JA11	MMTA - GI/GU - Low	Early - Community	0	3	0.9559
1JA21	MMTA - GI/GU - Low	Early - Community	1	3	1.0066
1JA31	MMTA - GI/GU - Low	Early - Community	2	3	1.1032
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	3	1.1360
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	3	1.1867
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	4	1.2833
3JA11	MMTA - GI/GU - Low	Late - Community	0	2	0.5498
3JA21	MMTA - GI/GU - Low	Late - Community	1	2	0.6005
3JA31	MMTA - GI/GU - Low	Late - Community	2	2	0.6972
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	3	0.9973
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	3	1.0480
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	3	1.1446
1JB11	MMTA - GI/GU - Medium	Early - Community	0	4	1.1106
1JB21	MMTA - GI/GU - Medium	Early - Community	1	4	1.1614
1JB31	MMTA - GI/GU - Medium	Early - Community	2	4	1.2580
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	4	1.2907
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	4	1.3415
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	4	1.4381
3JB11	MMTA - GI/GU - Medium	Late - Community	0	2	0.7046
3JB21	MMTA - GI/GU - Medium	Late - Community	1	2	0.7553
3JB31	MMTA - GI/GU - Medium	Late - Community	2	2	0.8520
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	3	1.1520
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	3	1.2028
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	4	1.2994
1KC11	MMTA - Infectious - High	Early - Community	0	3	1.2283
1KC21	MMTA - Infectious - High	Early - Community	1	3	1.2790

1KC31	MMTA - Infectious - High	Early - Community	2	3	1.3757
2KC11	MMTA - Infectious - High	Early - Institutional	0	3	1.4084
2KC21	MMTA - Infectious - High	Early - Institutional	1	3	1.4591
2KC31	MMTA - Infectious - High	Early - Institutional	2	4	1.5558
3KC11	MMTA - Infectious - High	Late - Community	0	2	0.8222
3KC21	MMTA - Infectious - High	Late - Community	1	2	0.8730
3KC31	MMTA - Infectious - High	Late - Community	2	2	0.9696
4KC11	MMTA - Infectious - High	Late - Institutional	0	3	1.2697
4KC21	MMTA - Infectious - High	Late - Institutional	1	3	1.3204
4KC31	MMTA - Infectious - High	Late - Institutional	2	3	1.4171
1KA11	MMTA - Infectious - Low	Early - Community	0	3	0.9888
1KA21	MMTA - Infectious - Low	Early - Community	1	3	1.0396
1KA31	MMTA - Infectious - Low	Early - Community	2	3	1.1362
2KA11	MMTA - Infectious - Low	Early - Institutional	0	3	1.1689
2KA21	MMTA - Infectious - Low	Early - Institutional	1	3	1.2197
2KA31	MMTA - Infectious - Low	Early - Institutional	2	4	1.3163
3KA11	MMTA - Infectious - Low	Late - Community	0	2	0.5828
3KA21	MMTA - Infectious - Low	Late - Community	1	2	0.6335
3KA31	MMTA - Infectious - Low	Late - Community	2	2	0.7301
4KA11	MMTA - Infectious - Low	Late - Institutional	0	2	1.0302
4KA21	MMTA - Infectious - Low	Late - Institutional	1	3	1.0810
4KA31	MMTA - Infectious - Low	Late - Institutional	2	3	1.1776
1KB11	MMTA - Infectious - Medium	Early - Community	0	3	1.1147
1KB21	MMTA - Infectious - Medium	Early - Community	1	3	1.1655
1KB31	MMTA - Infectious - Medium	Early - Community	2	4	1.2621
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	3	1.2948
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	4	1.3456
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	4	1.4422
3KB11	MMTA - Infectious - Medium	Late - Community	0	2	0.7087
3KB21	MMTA - Infectious - Medium	Late - Community	1	2	0.7594
3KB31	MMTA - Infectious - Medium	Late - Community	2	2	0.8560
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	3	1.1561
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	3	1.2069
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	4	1.3035
1AC11	MMTA - Other - High	Early - Community	0	4	1.2436
1AC21	MMTA - Other - High	Early - Community	1	4	1.2943
1AC31	MMTA - Other - High	Early - Community	2	4	1.3910
2AC11	MMTA - Other - High	Early - Institutional	0	4	1.4237
2AC21	MMTA - Other - High	Early - Institutional	1	4	1.4744
2AC31	MMTA - Other - High	Early - Institutional	2	5	1.5711
3AC11	MMTA - Other - High	Late - Community	0	2	0.8375

3AC21	MMTA - Other - High	Late - Community	1	2	0.8883
3AC31	MMTA - Other - High	Late - Community	2	2	0.9849
4AC11	MMTA - Other - High	Late - Institutional	0	3	1.2850
4AC21	MMTA - Other - High	Late - Institutional	1	3	1.3357
4AC31	MMTA - Other - High	Late - Institutional	2	3	1.4324
1AA11	MMTA - Other - Low	Early - Community	0	4	1.0124
1AA21	MMTA - Other - Low	Early - Community	1	4	1.0631
1AA31	MMTA - Other - Low	Early - Community	2	4	1.1597
2AA11	MMTA - Other - Low	Early - Institutional	0	3	1.1925
2AA21	MMTA - Other - Low	Early - Institutional	1	3	1.2432
2AA31	MMTA - Other - Low	Early - Institutional	2	3	1.3398
3AA11	MMTA - Other - Low	Late - Community	0	2	0.6063
3AA21	MMTA - Other - Low	Late - Community	1	2	0.6570
3AA31	MMTA - Other - Low	Late - Community	2	2	0.7537
4AA11	MMTA - Other - Low	Late - Institutional	0	3	1.0538
4AA21	MMTA - Other - Low	Late - Institutional	1	3	1.1045
4AA31	MMTA - Other - Low	Late - Institutional	2	3	1.2011
1AB11	MMTA - Other - Medium	Early - Community	0	5	1.1454
1AB21	MMTA - Other - Medium	Early - Community	1	5	1.1962
1AB31	MMTA - Other - Medium	Early - Community	2	4	1.2928
2AB11	MMTA - Other - Medium	Early - Institutional	0	4	1.3255
2AB21	MMTA - Other - Medium	Early - Institutional	1	4	1.3763
2AB31	MMTA - Other - Medium	Early - Institutional	2	5	1.4729
3AB11	MMTA - Other - Medium	Late - Community	0	2	0.7394
3AB21	MMTA - Other - Medium	Late - Community	1	2	0.7901
3AB31	MMTA - Other - Medium	Late - Community	2	3	0.8867
4AB11	MMTA - Other - Medium	Late - Institutional	0	3	1.1868
4AB21	MMTA - Other - Medium	Late - Institutional	1	3	1.2376
4AB31	MMTA - Other - Medium	Late - Institutional	2	4	1.3342
1LC11	MMTA - Respiratory - High	Early - Community	0	4	1.2089
1LC21	MMTA - Respiratory - High	Early - Community	1	4	1.2596
1LC31	MMTA - Respiratory - High	Early - Community	2	4	1.3563
2LC11	MMTA - Respiratory - High	Early - Institutional	0	4	1.3890
2LC21	MMTA - Respiratory - High	Early - Institutional	1	4	1.4398
2LC31	MMTA - Respiratory - High	Early - Institutional	2	4	1.5364
3LC11	MMTA - Respiratory - High	Late - Community	0	2	0.8029
3LC21	MMTA - Respiratory - High	Late - Community	1	2	0.8536
3LC31	MMTA - Respiratory - High	Late - Community	2	3	0.9502
4LC11	MMTA - Respiratory - High	Late - Institutional	0	3	1.2503
4LC21	MMTA - Respiratory - High	Late - Institutional	1	3	1.3010
4LC31	MMTA - Respiratory - High	Late - Institutional	2	3	1.3977

1LA11	MMTA - Respiratory - Low	Early - Community	0	4	0.9633
1LA21	MMTA - Respiratory - Low	Early - Community	1	4	1.0141
1LA31	MMTA - Respiratory - Low	Early - Community	2	4	1.1107
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	4	1.1434
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	4	1.1942
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	4	1.2908
3LA11	MMTA - Respiratory - Low	Late - Community	0	2	0.5573
3LA21	MMTA - Respiratory - Low	Late - Community	1	2	0.6080
3LA31	MMTA - Respiratory - Low	Late - Community	2	2	0.7047
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	3	1.0047
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	3	1.0555
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	3	1.1521
1LB11	MMTA - Respiratory - Medium	Early - Community	0	4	1.1011
1LB21	MMTA - Respiratory - Medium	Early - Community	1	5	1.1518
1LB31	MMTA - Respiratory - Medium	Early - Community	2	5	1.2484
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	4	1.2812
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	4	1.3319
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	5	1.4285
3LB11	MMTA - Respiratory - Medium	Late - Community	0	2	0.6950
3LB21	MMTA - Respiratory - Medium	Late - Community	1	2	0.7457
3LB31	MMTA - Respiratory - Medium	Late - Community	2	2	0.8424
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	3	1.1425
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	3	1.1932
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	4	1.2898
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	4	1.2226
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	5	1.2733
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	4	1.3700
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	5	1.4027
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	5	1.4535
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	5	1.5501
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	2	0.8166
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	2	0.8673
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	2	0.9639
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	4	1.2640
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	4	1.3147
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	4	1.4114
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	3	0.9117
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	3	0.9624
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	4	1.0591
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	3	1.0918

2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	4	1.1426
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	4	1.2392
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	2	0.5057
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	2	0.5564
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	2	0.6530
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	3	0.9531
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	3	1.0038
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	4	1.1005
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	4	1.0647
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	4	1.1154
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	5	1.2121
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	4	1.2448
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	5	1.2956
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	5	1.3922
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	2	0.6587
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	2	0.7094
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	2	0.8060
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	3	1.1061
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	4	1.1568
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	4	1.2535
1EC11	MS Rehab - High	Early - Community	0	5	1.3465
1EC21	MS Rehab - High	Early - Community	1	5	1.3972
1EC31	MS Rehab - High	Early - Community	2	5	1.4938
2EC11	MS Rehab - High	Early - Institutional	0	6	1.5266
2EC21	MS Rehab - High	Early - Institutional	1	6	1.5773
2EC31	MS Rehab - High	Early - Institutional	2	6	1.6739
3EC11	MS Rehab - High	Late - Community	0	2	0.9404
3EC21	MS Rehab - High	Late - Community	1	2	0.9911
3EC31	MS Rehab - High	Late - Community	2	3	1.0878
4EC11	MS Rehab - High	Late - Institutional	0	4	1.3879
4EC21	MS Rehab - High	Late - Institutional	1	4	1.4386
4EC31	MS Rehab - High	Late - Institutional	2	5	1.5352
1EA11	MS Rehab - Low	Early - Community	0	5	1.0813
1EA21	MS Rehab - Low	Early - Community	1	5	1.1321
1EA31	MS Rehab - Low	Early - Community	2	5	1.2287

2EA11	MS Rehab - Low	Early - Institutional	0	5	1.2614
2EA21	MS Rehab - Low	Early - Institutional	1	5	1.3122
2EA31	MS Rehab - Low	Early - Institutional	2	5	1.4088
3EA11	MS Rehab - Low	Late - Community	0	2	0.6753
3EA21	MS Rehab - Low	Late - Community	1	2	0.7260
3EA31	MS Rehab - Low	Late - Community	2	2	0.8226
4EA11	MS Rehab - Low	Late - Institutional	0	4	1.1227
4EA21	MS Rehab - Low	Late - Institutional	1	3	1.1735
4EA31	MS Rehab - Low	Late - Institutional	2	4	1.2701
1EB11	MS Rehab - Medium	Early - Community	0	5	1.1915
1EB21	MS Rehab - Medium	Early - Community	1	5	1.2422
1EB31	MS Rehab - Medium	Early - Community	2	5	1.3389
2EB11	MS Rehab - Medium	Early - Institutional	0	5	1.3716
2EB21	MS Rehab - Medium	Early - Institutional	1	6	1.4223
2EB31	MS Rehab - Medium	Early - Institutional	2	6	1.5190
3EB11	MS Rehab - Medium	Late - Community	0	2	0.7854
3EB21	MS Rehab - Medium	Late - Community	1	2	0.8362
3EB31	MS Rehab - Medium	Late - Community	2	3	0.9328
4EB11	MS Rehab - Medium	Late - Institutional	0	4	1.2329
4EB21	MS Rehab - Medium	Late - Institutional	1	4	1.2836
4EB31	MS Rehab - Medium	Late - Institutional	2	4	1.3803
1BC11	Neuro - High	Early - Community	0	5	1.4548
1BC21	Neuro - High	Early - Community	1	5	1.5055
1BC31	Neuro - High	Early - Community	2	5	1.6021
2BC11	Neuro - High	Early - Institutional	0	5	1.6349
2BC21	Neuro - High	Early - Institutional	1	5	1.6856
2BC31	Neuro - High	Early - Institutional	2	5	1.7823
3BC11	Neuro - High	Late - Community	0	2	1.0487
3BC21	Neuro - High	Late - Community	1	3	1.0994
3BC31	Neuro - High	Late - Community	2	3	1.1961
4BC11	Neuro - High	Late - Institutional	0	4	1.4962
4BC21	Neuro - High	Late - Institutional	1	4	1.5469
4BC31	Neuro - High	Late - Institutional	2	4	1.6435
1BA11	Neuro - Low	Early - Community	0	5	1.1928
1BA21	Neuro - Low	Early - Community	1	5	1.2435
1BA31	Neuro - Low	Early - Community	2	4	1.3401
2BA11	Neuro - Low	Early - Institutional	0	5	1.3729
2BA21	Neuro - Low	Early - Institutional	1	5	1.4236
2BA31	Neuro - Low	Early - Institutional	2	5	1.5203
3BA11	Neuro - Low	Late - Community	0	2	0.7867
3BA21	Neuro - Low	Late - Community	1	2	0.8374

3BA31	Neuro - Low	Late - Community	2	2	0.9341
4BA11	Neuro - Low	Late - Institutional	0	3	1.2342
4BA21	Neuro - Low	Late - Institutional	1	4	1.2849
4BA31	Neuro - Low	Late - Institutional	2	4	1.3815
1BB11	Neuro - Medium	Early - Community	0	5	1.3525
1BB21	Neuro - Medium	Early - Community	1	5	1.4032
1BB31	Neuro - Medium	Early - Community	2	5	1.4998
2BB11	Neuro - Medium	Early - Institutional	0	6	1.5326
2BB21	Neuro - Medium	Early - Institutional	1	6	1.5833
2BB31	Neuro - Medium	Early - Institutional	2	6	1.6800
3BB11	Neuro - Medium	Late - Community	0	2	0.9464
3BB21	Neuro - Medium	Late - Community	1	2	0.9971
3BB31	Neuro - Medium	Late - Community	2	3	1.0938
4BB11	Neuro - Medium	Late - Institutional	0	4	1.3939
4BB21	Neuro - Medium	Late - Institutional	1	4	1.4446
4BB31	Neuro - Medium	Late - Institutional	2	5	1.5412
1CC11	Wound - High	Early - Community	0	5	1.5156
1CC21	Wound - High	Early - Community	1	5	1.5663
1CC31	Wound - High	Early - Community	2	5	1.6629
2CC11	Wound - High	Early - Institutional	0	5	1.6957
2CC21	Wound - High	Early - Institutional	1	5	1.7464
2CC31	Wound - High	Early - Institutional	2	5	1.8430
3CC11	Wound - High	Late - Community	0	3	1.1095
3CC21	Wound - High	Late - Community	1	3	1.1602
3CC31	Wound - High	Late - Community	2	3	1.2569
4CC11	Wound - High	Late - Institutional	0	4	1.5570
4CC21	Wound - High	Late - Institutional	1	4	1.6077
4CC31	Wound - High	Late - Institutional	2	4	1.7043
1CA11	Wound - Low	Early - Community	0	5	1.2468
1CA21	Wound - Low	Early - Community	1	4	1.2976
1CA31	Wound - Low	Early - Community	2	4	1.3942
2CA11	Wound - Low	Early - Institutional	0	4	1.4269
2CA21	Wound - Low	Early - Institutional	1	4	1.4777
2CA31	Wound - Low	Early - Institutional	2	4	1.5743
3CA11	Wound - Low	Late - Community	0	2	0.8408
3CA21	Wound - Low	Late - Community	1	3	0.8915
3CA31	Wound - Low	Late - Community	2	3	0.9881
4CA11	Wound - Low	Late - Institutional	0	3	1.2882
4CA21	Wound - Low	Late - Institutional	1	3	1.3390
4CA31	Wound - Low	Late - Institutional	2	3	1.4356
1CB11	Wound - Medium	Early - Community	0	5	1.3911

1CB21	Wound - Medium	Early - Community	1	5	1.4418
1CB31	Wound - Medium	Early - Community	2	5	1.5385
2CB11	Wound - Medium	Early - Institutional	0	5	1.5712
2CB21	Wound - Medium	Early - Institutional	1	5	1.6219
2CB31	Wound - Medium	Early - Institutional	2	5	1.7186
3CB11	Wound - Medium	Late - Community	0	3	0.9850
3CB21	Wound - Medium	Late - Community	1	3	1.0358
3CB31	Wound - Medium	Late - Community	2	3	1.1324
4CB11	Wound - Medium	Late - Institutional	0	4	1.4325
4CB21	Wound - Medium	Late - Institutional	1	4	1.4832
4CB31	Wound - Medium	Late - Institutional	2	4	1.5799

Source: CY 2018 Medicare claims data for episodes ending on or before December 31, 2018 (as of July 31, 2019) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

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The following is a summary of the comments received and our responses to comments on the CY 2020 PDGM LUPA Thresholds and PDGM Case-Mix Weights.

Comment: A few commenters stated that the case mix weights for clinical groups that include therapy services are significantly depressed from the weights that would be assigned if CMS continued to use BLS data. These commenters expressed concern that there is a reduction in payment rates for therapy clinical groups and this would create barriers to care for patients needing therapy. These commenters urged CMS to continue to use BLS data for determining the PDGM case-mix weights.

Response: We finalized the CPM+NRS approach to calculating the costs of care in the CY 2019 HH PPS final rule with comment period and in that rule we stated that we believe that the use of HHA Medicare cost reports better reflects changes in utilization, provider payments, and supply amongst Medicare-certified HHAs that occur over time. Under a Wage-Weighted Minutes of Care (WWMC) approach, using the BLS average hourly wage rates for the entire home health care service industry does not reflect changes in Medicare home health utilization that impact costs, such as the allocation of overhead costs when Medicare home health visit patterns change. Using data from HHA Medicare cost reports better represents the total costs incurred during a 30-day period (including, but not limited to, direct patient care contract labor, overhead, and transportation costs), while the WWMC method provides an estimate of only the labor costs (wage and fringe benefit costs) related to direct patient care from patient visits that are incurred during a 30-day period. We will recalibrate the case-mix weights annually, as is currently done, to ensure that the case-mix weights accurately align with the cost of providing care.

Comment: A commenter recognized the long-term improvement of the LUPA proposal to align low acuity episodes with a lower LUPA threshold while high-acuity episodes would have higher LUPA threshold. A few commenters stated that the LUPA thresholds are confusing and recommended a more straightforward approach to pay for LUPAs. Another commenter remarked that there were some institutional admission source LUPA thresholds that had less number of visits to meet the threshold than their community admission source counterparts and questioned if this was accurate. This commenter also stated that other institutional admission source thresholds were only one visit more than their community admission source counterpart and that this seems incorrect if institutional admission sources have higher resource costs than community admission sources.

Response: Because of the change in the unit of payment from a 60-day episode to a 30-day period, the approach to calculating the LUPA thresholds needed to change in order to target approximately the same percentage of LUPAs. As we discussed in both the CYs 2018 and 2019 HH PPS proposed rules, 30-day periods of care have substantially more episodes with four or fewer visits than 60-day episodes. To create LUPA thresholds for 30-day periods of care, we finalized in the CY 2019 final rule with comment period to set the LUPA threshold at the 10th percentile value of visits or 2, whichever is higher, for each payment group, in order to target approximately the same percentage of LUPAs (approximately 7.1 percent of 30-day periods would be LUPAs (assuming no behavior change)) (83 FR 56492). We note that under the current HH PPS, LUPA episodes are billed the same as a non-LUPA episodes and this will not change under the PDGM where LUPA periods of care will be billed the same way as non-LUPA 30-day periods of care; therefore, we do not believe that this would cause any confusion related to billing.

The commenter is correct that there are some institutional admission source LUPA thresholds that are less than their community counterparts. The LUPA threshold does not necessarily relate to the case-mix weight of the 30-day period. For example, looking at the case-mix group, Behavioral Health—Low Functional Impairment, Early Timing, Low Comorbidity Adjustment:

- Community 30-day periods have an average resource use of $1,655.70 and a LUPA threshold of 4 visits.
- Institutional 30-day periods have average resource use of $1,804.17 and a LUPA threshold of 3 visits.

We remind commenters that we finalized the policy for the PDGM LUPA thresholds to target approximately the same percentage of LUPAs as under the 153 case-mix weight system using the criteria noted previously. We continue to believe that the LUPA thresholds that vary based on the case-mix assignment for the 30-day period of care in the proposed PDGM is an improvement over the current 5 visit threshold that does not vary by case-mix assignment. Likewise, in the CY 2019 HH PPS final rule with comment period (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.

Final Decision: We are maintaining our finalized policy in the CY 2019 HH PPS final rule with comment period (83 FR 56492) to vary the LUPA thresholds for each 30-day period of care depending on the PDGM payment group to which it is assigned. Additionally, we are finalizing the CY 2020 LUPA thresholds and case-mix weights as shown in Table 16 in this final rule with comment period. We will continue to update the LUPA thresholds by payment group and will annually recalibrate the case-mix weights using the most current data available at the time of rulemaking.

E. CY 2020 Home Health Payment Rate Updates

1. 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 with comment period (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 with comment period (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 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 2.9 percent (based on IHS Global Insight Inc.'s third-quarter 2019 forecast). However, 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 2.9 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 0.3 percentage point for CY 2020. In effect, the 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 will 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 proposed 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 proposed 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 proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we proposed to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we proposed to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2020, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). The CY 2020 wage index value for Hinesville, GA is 0.8322.

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 0.8291. The August 15, 2017 Bulletin No. 17–01, Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas, is available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

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.*

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 Home Health Prospective Payment System Regulations and Notices web page: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.*

We received 1 comment regarding the CY 2020 Home Health wage index. The comment and our response appear in this section of this final rule with comment period:

Comment: A commenter questioned the validity of the CY 2020 wage index data in the case of the CBSA for Albany-Schenectady-Troy, noting that in the past 6 years, this CBSA has seen its wage index reduced 5.17 percent, going from 0.8647 in 2013 to a proposed CY 2020 wage index of 0.820. This commenter also suggests that the Albany-Schenectady-Troy CBSA should not be lower than any of the following other upstate New York CBSAs: Binghamton, Elmira, Glen Falls, Rochester, Syracuse, Watertown-Fort Drum and, most significantly, the ''New York Rural Areas CBSA,'' which is proposed to be 0.8431.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The area wage index measures differences in hospital wage rates among labor market areas and compares the area wage index of the labor market area to the national average hourly wage. If a hospital or labor market area does not keep pace with the national average hourly wage in a given year, then the labor market area will see a decrease in the area wage index during that year.

We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. Hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. Medicare contractors perform desk reviews on all hospitals' Worksheet S– 3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. If any provider believes the underlying hospital wage data is inaccurate, the data would have to be corrected by the Medicare Administrative Contractor (MAC) within the necessary timeframe in order for the error to be corrected; otherwise the data would be deemed final for that upcoming year's wage index. The time table used for the development of the FY 2020 hospital wage index can be found at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2020-Hospital-Wage-Index-Development-Time-Table.pdf.* We believe that our review processes result in an accurate reflection of the applicable wages for the areas given.

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 solicited 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.

The following is a summary of the comments received on the proposed CY 2020 home health wage index comment solicitation, and our responses:

Comment: A few commenters recommended that the wage index account for areas with higher minimum wage standards. A commenter stated that the pre-floor, pre-reclassified hospital wage index is ''wholly inadequate for adjusting home health costs, particularly in states like New York which has among the nation's highest labor costs now greatly exacerbated by the states implementation of a phased in $15 per hour minimum wage hike, the balance of which is unfunded by Medicare.'' Another commenter suggested that CMS develop a reimbursement system adjustment providing supplemental funding to providers, such as HHAs, required to meet higher minimum wage standards, better to align reimbursement rates with cost trends impacting these providers.

Response: Regarding minimum wage standards, we note that such increases would be reflected in future data used to create the hospital wage index to the extent that these changes to state minimum wage standards are reflected in increased wages to hospital staff.

Comment: Several commenters recommended that CMS consider consulting with home health agencies to develop a home health specific wage index or explore opportunities to improve the wage index applied to home health. A commenter urges CMS to consider a home health specific wage index to support staff retention due to increased demands on meeting paperwork and regulatory requirements. The commenter notes that the current home health wage index is tied to hospital wage data, which does not reflect the true cost of hiring and retaining high quality home health staff. Another commenter suggested that CMS use home health specific data contained in home health cost reports, which contain average cost per visit. A commenter recommended that CMS use the post-reclassified wage index values for each CBSA. Another commenter indicated that ''CMS should include wage data from reclassified hospitals in calculating the rural wage index for home health agencies.'' The same commenter indicated that CMS should examine how population density impacts home health agency costs and then adjust the wage index by multiplying by a population density factor so that areas with a lower population density have a higher adjusted wage index. A few commenters indicated that an approach similar to that used in the FY 2020 Inpatient Hospital PPS final rule should be used, where hospitals with a wage index value that was less than the 25th percentile had their wage index increased. A commenter also suggested that a wage index floor should be established similar to the 0.8 hospice wage index floor.

Response: We thank the commenters for their comments. We will consider these recommendations for future rulemaking.

Final Decision: After considering the comments received in response to the CY 2020 HH PPS proposed rule, we are finalizing our proposal to continue to use the pre-floor, pre-reclassified

hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2020, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2015 and before October 1, 2016 (FY 2016 cost report data). The final CY 2020 wage index is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*.

4. CY 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 with comment period (83 FR 56406) and as described in section III.B of this 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 after January 1, 2020. As such, the latest date such a 60-day crossover episode could end on is February 28, 2020. Those 60-day crossover 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 17.

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 with comment period (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 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 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.G. of this 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) 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.E. of this rule. We did not propose to update the case-mix weights for the 153-group case-mix methodology in CY 2020 as outlined in section III.D. of this rule. Because we will use the CY 2019 case-mix weights, we do not 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 final 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 1.0060. We apply the wage index budget neutrality factor of 1.0060 to the calculation of the CY 2020 national, standardized 60-day episode payment rate.

Next, we 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 rule. The CY 2020 national, standardized 60-day episode payment rate is calculated in Table 17.

TABLE 17: 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 1.0060	X 1.015	$3,220.79

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 18.

TABLE 18: 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 1.0060	X 0.995	$3,157.33

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 NRS conversion factor for CY 2020 is shown in Table 19.

TABLE 19: 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 20.

TABLE 20: 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 2020 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 CY 2020 NRS conversion factor for HHAs that do not submit quality data is shown in Table 21.

TABLE 21: 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 22.

TABLE 22 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 in CY 2020, on or before 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. of this final rule with comment period.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA 30-day periods

using the final CY 2020 wage index and compared it to our simulation of total payments for non-LUPA 30-day periods using the CY 2019 wage index. By dividing the total payments for non-LUPA 30-day periods using the CY 2020 wage index by the total payments for non-LUPA 30-day periods using the CY 2019 wage index, we obtain a wage index budget neutrality factor of 1.0063. We would apply the wage index budget neutrality factor of 1.0063 to the calculation of the CY 2020 national, standardized 30-day period payment rate as described in section III.B. of this 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, a case-mix budget neutrality factor is not applicable. 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 estimated change in aggregate payments between the previous year's PDGM case-mix weights and the recalibrated PDGM case-mix weights.

Next, we 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.E. of this final rule with comment period. The CY 2020 national, standardized 30-day period payment rate is calculated in Table 23.

TABLE 23: CY 2020 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2019 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
$1,824.99	X 1.0063	X 1.015	$1,864.03

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 24.

TABLE 24: 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
$1,824.99	X 1.0063	X 0.995	$1,827.30

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 weight 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 25.

TABLE 25: 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 1.0066	X 1.015	$ 67.78
Medical Social Services	$234.82	X 1.0066	X 1.015	$239.92
Occupational Therapy	$161.24	X 1.0066	X 1.015	$164.74
Physical Therapy	$160.14	X 1.0066	X 1.015	$163.61
Skilled Nursing	$146.50	X 1.0066	X 1.015	$149.68
Speech-Language Pathology	$174.06	X 1.0066	X 1.015	$177.84

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 26.

TABLE 26: 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 1.0066	X 0.995	$66.44
Medical Social Services	$234.82	X 1.0066	X 0.995	$235.19
Occupational Therapy	$161.24	X 1.0066	X 0.995	$161.49
Physical Therapy	$160.14	X 1.0066	X 0.995	$160.39
Skilled Nursing	$146.50	X 1.0066	X 0.995	$146.73
Speech- Language Pathology	$174.06	X 1.0066	X 0.995	$174.33

Final Decision: We did not receive any comments on the CY 2020 home health payment rate update for CY 2020. Therefore, we are finalizing the 60-day episode payment rates for those episodes of care that span the January 1, 2020 implementation date of the change to a 30-day unit of payment; the 30-day period payment rates for periods of care beginning on and after January 1, 2020; the CY 2020 per-visit payment rates; and the home health update percentage to update the home health payment rates for CY 2020 as proposed.

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 with comment period (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 associated with the publication of this rule is available in the ''Downloads'' section of the Home Health Prospective Payment System Regulations and Notices web page. 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 on the same web page.

The HH PRICER module, located within CMS' claims processing system, will increase the final CY 2020 60-day and 30-day base payment rates described in section III.E. of this 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 27.

TABLE 27: 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

While we did not solicit comments on the rural add-on percentages as these are mandated by the BBA of 2018, we did receive a few comments, mainly from rural HHAs. These are summarized in this section of this final rule with comment period.

Comment: MedPAC supports CMS's proposal that recognizes high-utilization counties, low-population counties, and all other counties to apply to rural add-on to remain in effect until CY 2022. MedPAC has not found systematic issues with access to home health care in rural areas nor concerns regarding rural home health margins. Furthermore, CMS's rural add-on policy supports MedPAC's recommendation to target rural payment adjustments to areas that have access challenges.

Response: We thank MedPAC for their support.

Comment: Several commenters recognized that the phase-out of the rural add-on is based on the Bipartisan Budget Act of 2018 with no latitude to revise the proposal. However, they suggested CMS take this into consideration in relation to the 8.01 percent reduction in the standardized 30-day rate to account for behavioral adjustments. Some commenters indicate the phase-out of the rural add-on payment, coupled with other payment system changes, would be difficult for rural HHAs to fiscally manage. Commenters indicated that CMS should monitor the impact of the phase-out (and determine if counties experience demographic changes year to year) and publicly report findings. A commenter recommended continued monitoring during the PDGM post-implementation period in order to determine the impact on accessibility to care and the ability of providers to fill open staffing positions.

Response: We understand commenter concerns about a phase-out of rural add-on payments and potential effects on rural HHAs. However, because the current rural add-on policy is statutory, we have no regulatory discretion to extend it. Congress would need to change the law. Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating a 30-day payment amount in a budget-neutral manner, the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the new case-mix adjustment methodology. We remind commenters that the overall impact of the PDGM, the 30-day unit of payment, and behavioral assumptions is zero given the statutory requirement that these changes are implemented in a budget-neutral manner. CMS will continue to monitor patient access to home health services, as well as the costs associated with providing home health care in rural versus urban areas, and the impacts due to policy changes, including the changes in rural add-on payments for CYs 2019 through 2022. We will provide the industry with periodic updates on our analysis in rulemaking and/or announcements on the HHA Center web page at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html*.

Comment: Several commenters indicated that CMS should continue to ensure beneficiaries living in rural areas have adequate access to the home health benefit. Some commenters indicated

that CMS should consider providing coverage for telehealth services related to therapy.

Response: We thank commenters for their suggestions as it relates to telehealth services. Section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in person home health services ordered as part of a plan of care certified by a physician. Thus, virtual home health visits would not qualify for payment under the home health benefit. We will continue to examine the role of telehealth under the home health benefit and will consider ways to more broadly support such technology as a part of the home health benefit when used to augment the plan of care, but not replace in-person visits.

Final Decision: Policies for the provision of rural add-on payments for CY 2019 through CY 2022 were finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56443), in accordance with section 50208 of the BBA of 2018. The data used to categorize each county or equivalent area are 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 CY 2020 through 2022 rural add-on percentages outlined in law are shown in Table 27.

We are not making any changes to the policies previously finalized in last year's rulemaking in this final rule with comment period.

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 with comment (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 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 $276.17 (1.8451 multiplied by $149.68), subject to area wage adjustment.

Also in the CY 2019 HH PPS final rule with comment period (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.

Final Decision: We did not receive any comments on the LUPA add-on factors or partial payment adjustments. Therefore, as finalized in the CY 2019 final rule with comment period, we will continue to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. We will also retain the current PEP policy and apply such policy to 30-day periods of care under the PDGM.

F. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or partial episode payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the HH FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost 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.

Tables 25 and 26 show the CY 2020 per-visit payment rates and we will 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 with comment period. 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 with comment period (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. 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 with comment period (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 did not propose to update the FDL ratio for those 60-day episodes that span the implementation date of the PDGM and the change to a 30-day unit of payment. For those 30-day periods of care in CY 2020, we proposed that the FDL ratio would need to be set at 0.63 in order for outlier payments not to exceed 2.5 percent of the total payments estimated to be made under the HH PPS. In this final rule with comment period, we updated the outlier estimates for 30-day periods of care beginning on and after January 1, 2020 using updated claims data and the final CY 2020 payment rates outlined in section III.E.4 of this final rule with comment period. 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, the FDL ratio for 30-day periods of care in CY 2020 would need to be set at 0.56 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 we updated 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 July 31, 2019) and

therefore, the final FDL ratio has been updated accordingly.

Final Decision: We did not receive any comments on the proposed FDL ratios for 60-day episodes of care that span the January 1, 2020 implementation date of the PDGM and the change to a 30-day unit of payment or for 30-day periods of care. Therefore, we are finalizing the FDL ratio of 0.51 for 60-day episodes and 0.56 for 30-day periods of care for CY 2020.

G. Changes to the Split-Percentage Payment Approach for HHAs in CY 2020 and Subsequent Years

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 of care 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 in the common working file (CWF) so that the claims processing system can reject claims from providers or suppliers other than the primary HHA for the services and items subject to consolidated billing. As noted previously, section 1895(b)(2)(B) of the Act, as added by section 51001(a) of the BBA of 2018, requires a change in the unit of payment from a 60 days to 30 days, effective January 1, 2020. As such, in the CY 2019 HH PPS proposed rule (83 FR 32391) and in this year's CY 2020 HH PPS proposed rule (84 FR 34598), we discussed our belief that the split percentage approach to payment may no longer be needed for HHAs to maintain adequate cash flow.

In the CY 2019 HH PPS final rule with comment period (83 FR 56628), we discussed the typical RAP fraud scenario where an HHA enrolls in Medicare and proceeds to submit a large amount of RAPs in a short timeframe, the provider never submits a final claim and then shuts down the business before CMS is able to take action. In light of the potential for this type of fraud scenario, and the move to a 30-day unit of payment where HHAs can submit the final claim after 30 days, 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.

In the CY 2020 HH PPS proposed rule (84 FR 34598), we described more recent fraud schemes with existing providers where individuals or groups with the intent of perpetuating fraud enter the program by acquiring existing HHAs which allows them to circumvent Medicare's screening and enrollment process. These individuals and groups purchase existing agencies through Changes of Ownerships (CHOWs) and Changes of Information, but fail to disclose ownership changes to CMS as required by 42 CFR 424.516(e) and 489.18 (as applicable). If CMS identifies the failure to report, it can revoke the enrollment of the HHA in the Medicare program under 42 CFR 424.535(a)(1) (or under 42 CFR 424.535(a)(9) after the FY 2020 Program Integrity Enhancements to the Provider Enrollment Process final rule with comment period (84 FR 47794) is effective on November 4, 2019). However, problematic individuals or groups that engage in the above intentional reporting failures may not always be identified and, thus, CMS may not be able to remove the bad actors from the program in all relevant cases.

A situation like this, where an individual or group acquires existing HHAs and does not appropriately disclose ownership relationships to CMS, allows the individual or groups who have acquired the HHA to evade the normal enrollment screening processes enabling them to operate as if they are an existing provider. Situations like this leave CMS blind to the potentially problematic criminal history of the acquiring individual.

In order to address program integrity vulnerabilities for situations like this, as well as those where providers enroll and flood the system with RAPs solely to collect the upfront payment and never submit a final claim, we proposed in the CY 2020 HH PPS proposed rule (84 FR 34598) to lower the upfront split percentage payment from the current 60/50 percent (depending on whether period of care is the initial or subsequent period) to 20 percent in CY 2020 for both initial and subsequent 30-day periods of care and proposed to eliminate RAPs for all providers starting in CY 2021. Also, after the sunset of the RAP policy in CY 2021, we proposed to require all HHAs to submit a one-time NOA, within 5 calendar days from the start of care date, to establish that the beneficiary is under a Medicare home health period of care and also to trigger home health consolidated billing edits required under section 1842(b)(6)(F) of the Act. Moreover, we proposed that failure to submit a timely NOA, that is not submitting the NOA within 5 calendar days from the start of care date, would result in a reduction to the 30-day Medicare payment amount. We proposed that Medicare would not pay for days of home health services from the start of care date to the NOA filing date if the NOA was submitted after the 5 calendar day deadline. Likewise, we proposed 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 also proposed that if an exceptional circumstance is experienced by the HHA, CMS may waive the consequences of failure to submit a timely-filed NOA. Lastly, we proposed corresponding regulation text changes at § 484.205.

The following is a summary of the public comments received on the ''Split Percentage Payment Approach for a 30-day Unit of Payment'' and the ''Notice of Admission'' proposals and our responses:

Comment: Most commenters did not support the phase-out of the split percentage payment and suggested that CMS not change its current policy. Other commenters stated that CMS was implementing too many policy changes at once and requested additional time for implementation. Some commenters remarked that RAPs should continue under the PDGM to ensure there is no disruption in cash flow for providers as that would be harmful to their business. Other commenters stated that a split percentage payment phase-out should be postponed for HHAs in states that require Review Choice Demonstration (RCD) participation. There was also some commenter support to phase-out the split percentage payment over a multi-year period, starting at least one year after the implementation of the PDGM, in order to allow agencies of

various sizes and geographical designations to appropriately adapt to PDGM.

Response: We continue to believe that as a result of the change in the unit of payment from a 60-day episode of care to a 30-day period of care, that a split percentage approach to payment may not be needed for HHAs to maintain an adequate cash flow. With monthly billing, HHAs have the ability to receive ongoing cash flow which we believe would mitigate concerns over having adequate funds for the provision of care, no matter the size or geographical designation of the HHA. We note that for the first year of the PDGM in CY 2020, providers will still receive a RAP payment of 20 percent which should help transition existing providers to the new payment system. We also believe that the eventual phase-out of RAPs will significantly streamline claims processing for HHAs as they would not be submitting a RAP for each 30-day period of care and instead would submit a one-time NOA. Also, HHAs have capitalization requirements which requires the agency to have available sufficient funds at the time of applying for enrollment in Medicare, at all times during the enrollment process, and during the 3-month period following the conveyance of Medicare billing privileges to the HHA. A multi-year phase-out approach, which some commenters suggest, would not help streamline claims processing for providers nor would it address the ongoing program integrity issues that we have discussed in the CY 2019 HH PPS proposed and final rules (83 FR 32391 and 83 FR 56462, respectively) and in this year's CY 2020 HH PPS proposed rule (84 FR 34638). A multi-year approach would just continue to subject the Medicare Trust Fund to additional fraud schemes in relation to the submission of RAPs. However, we will continue to monitor HHA adaptation for the split percentage phase-out with the implementation of the PDGM, and may decide whether additional adjustments are necessary in future rulemaking if an access to care issue arises.

Comment: Many commenters had concerns that CMS was modifying its RAP policy due to abuse by certain agencies. Commenters suggested that CMS should utilize their ability to restrict RAPs for agencies that abuse it instead of modifying the current RAP policy. Other commenters stated that because CMS recoups the majority of RAP overpayments, RAP policy changes were unneeded. Some commenters indicated that not all cases where a final claim is not submitted after a RAP are abusive and that CMS should address actual abuse using tools such as post payment review and audits. Commenters encouraged CMS to identify the agencies that are abusing the system and to impose more oversight through accrediting organizations and the MACs. A commenter raised their concern that removal of RAPs would increase incidents of ''cherry picking.''

Response: While one of the reasons for the elimination of RAPs is to potentially stem program integrity vulnerabilities, it is not the sole reason. We remind commenters that the current median length of days for RAP submission is 12 days from the start of the 60-day episode of care. With a change in the unit of payment to a 30-day period of care, if this median length of days for RAP submissions remains constant, there is the possibility that HHAs could be simultaneously submitting a RAP and a final claim for each 30-day period of care. We believe that this defeats the purpose of the RAP to maintain adequate cash flow and only increases complexity for HHAs in their claims processing. With monthly billing, HHAs have the ability to receive an ongoing cash flow which we believe would mitigate concerns over having adequate funds for the provision of care.

CMS's use of post payment audit and review as a means to address abuse is not an appropriate intervention to prevent fraudulent or improper behavior because these are ''pay and chase'' solutions to a problem that demands preventive action. Post payment review and other auditing approaches are not always cost effective and as described in the proposed rule, they, by definition, are susceptible to significant program integrity abuses. We are moving beyond the pay and chase approach to program integrity structural changes wherever possible for all provider settings. To base our approach to home health program integrity on a pay and chase framework simply does not achieve the protections we need to have in place. Post payment audits and other post payment recoupment processes are not an acceptable modern technological solution for ensuring proper payment in the home health environment.

We acknowledge and appreciate the concerns commenters have raised with regards to abuse of the RAP policy by certain HHAs. We plan to continue to closely monitor RAP submissions, service utilization, payment, and quality trends which may change as a result of implementing of the PDGM and a 30-day unit of payment. If changes in practice and/or coding patterns or RAPs submissions arise, we may take further action, which may include administrative action against providers as appropriate and/or proposing changes in policy. We will also continue to work with the HHS Office of Inspector General as cases of potential provider fraud and abuse are identified.

Comment: A commenter requests CMS to clarify or identify the responsible party in a change of ownership (CHOW) when the RAP is eliminated. Another commenter stated their belief that agencies submitting RAPs would not have a limitless supply of cash and provided questions that, when answered, would pierce corporate protections and allow for civil prosecution.

Response: A change in ownership of a HHA does not change the RAP requirements. All home health agencies, including those that have undergone a change in ownership, will be subject to the elimination of RAPs when it occurs in CY 2022. Also, we believe that the new RAP policy does nothing to change any corporate protections or the rules regarding civil prosecution that exist currently.

The need for regulatory change to phase-out RAPs for existing providers is well supported by the spike in RAP fraud schemes perpetrated by existing providers. As discussed in the CY 2020 HH PPS proposed rule (84 FR 34598), 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 the Provider Enrollment, Chain and Ownership System (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 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, and the provider subsequently submitted a spike in RAP suppressions. All payments to the provider were suspended. Notwithstanding, the provider was paid $3.6 million in RAPs.

Although CMS has attempted to address these vulnerabilities through extensive monitoring, audits and investigations, there continue to be cases of individual HHAs causing large RAP fraud losses. Recently, a September 27, 2019 DOJ press release highlighted a number of charges brought against individuals involved in certain health care fraud schemes: *https://www.justice.gov/opa/pr/midwest-health-care-fraud-law-enforcement-action-results-charges-against-53-individuals*. We consider these fraudulent improper payments a significant vulnerability to the Medicare Trust Funds. We continue to believe that we need proactive interventions and approaches to prevent these kinds of events from happening, and that the financial impact to HHAs will be minimal under the change from a 60-day to 30-day episode of care. Likewise, we believe that the RAP phase-out and eventual elimination of split-percentage payments would serve to mitigate potential fraud schemes while minimally impacting HHAs due to the switch to a 30-day unit of payment.

Comment: A few commenters expressed support for the NOA and recognized that the NOA would be necessary to alert the claims processing system of a home health period of care due to the required consolidated billing requirements. Other commenters stated that the use of a NOA would place burden on HHAs in the form of additional paperwork/coordination, and that the NOA requirements were excessive and CMS should consider not requiring HHAs to complete the OASIS or acquiring a signed plan of care before accepting the NOA. Some commenters indicated that the only information that should be required to submit the NOA are items like the ''beneficiary's name and a start of care date'' and/or a verbal order to begin care. A commenter suggested that the NOA be optional in CY 2021 and mandatory in CY 2022.

Response: We thank those commenters for their support and recognition of the need for a NOA. Specifically, we agree that having a one-time submission of a NOA within 5 calendar days of the start of care, establishing that the beneficiary is under a Medicare home health period of care, will cut down on claims denials, help trigger consolidated billing edits sooner and may streamline claims processing for HHAs. The NOA also provides other HHAs the capability to determine if a beneficiary is already under a Medicare home health period of care; thereby, reduces the administrative burden associated with determining a beneficiary's period of care, reimbursement cancelations, and general beneficiary coordination issues. After reviewing all of the comments received regarding the information needed to submit the NOA, we agree with commenters that since the NOA does not have a payment tied to its submission, the requirements to fulfill the NOA should not mirror the requirements associated with the submission of a RAP. As such, we agree with commenters that the NOA submission criteria should require only the necessary information needed to begin Medicare home health services for the beneficiary. Therefore, the only information we will require for the NOA, starting in CY 2022, will be: (1) A written or verbal order from the physician (containing the services required for the initial visit) signed and dated by the physician, and if verbal, 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 signed by the physician; and (2) for the HHA to conduct the initial start of care visit. We believe these requirements represent the minimum amount of information that is sufficient for establishing a home health period of care and is information that the home health agency would already have as part of the medical record for beneficiaries admitted to home health.

Comment: Some commenters requested that CMS consider adopting a simple mechanism for timely notification, such as requiring HHAs to make notations in the CWF or through the EDI. Other commenters stated that submitting a NOA within 5 calendar days from the start of care is problematic and that many HHAs would be unable to meet that short timeframe. Instead of the 5 calendar day timely filing requirement, some commenters suggested lengthening the timeframe to 10–14 calendar days to submit a NOA. Other commenters recommended that CMS postpone the NOA requirements until CY 2022 or later, to allow HHAs time to adjust to the new PDGM 30-day unit of payment.

Response: There is currently no mechanism that would allow providers the ability to make any kind of notation in the CWF. Even if the creation of such a mechanism was feasible, the program integrity concerns of allowing providers to make their own notations in CWF would be exchanging one program integrity vulnerability (the upfront RAP payments) for another (allowing providers to make their own notations in the CWF). A NOA is needed to identify the initial home health period of care for each beneficiary after the elimination of RAPs. Failure to provide such notification, (which triggers the home health consolidated billing edits and establishes the home health period of care in the CWF), could lead to an increase in claims denials. Moreover, not having an NOA 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 provider. As we envision it, the home health NOA process would be operationalized through an EDI submission, similar to that used for submission of the hospice Notice of Election (NOE). The purpose of an EDI submission, for NOEs for hospice or NOAs for home health, is to minimize data entry errors. Because there is already a Medicare claims processing notification, for benefit admission, in place, we believe that this should make the home health NOA process more consistent and timely for HHAs. Additionally, the use of a one-time NOA would streamline HHAs claims processing as the need for submitting a RAP for every period of care would be eliminated. The HHA would only be submitting the NOA once at the start of care which would minimize provider administrative burden for each beneficiary whom the HHA provides home health services.

Concerning the 5 calendar day timely-filing requirement, CMS considered different time frames for the submission of the one-time NOA, including a 7 calendar day timeframe in which to submit a timely-filed NOA. However, to

be consistent with similar requirements in other settings (for example, in hospice where the NOE must be submitted within 5 calendar days), we believe the 5 calendar day timely-filing requirement would ensure that the Medicare claims processing system is alerted as soon as possible to mitigate any potential claims denials of other providers for services that should be covered under the home health benefit. Furthermore, the longer the NOA submission timeframe, the higher the uncertainty for providers to determine home health periods of care for a beneficiary. Having a policy for submitting a NOA within 5 calendar days, when compared to the commenter suggested 10–14 calendar days, will create an environment where there is less confusion and administrative burden for HHAs, when determining home health periods of care. After reviewing comments, we have decided to limit the requirements to submit the NOA to only require a verbal order from the physician (containing the services required for the initial visit) 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 signed by the physician, and that the HHA conduct the start of care visit. Also, in response to comments received, as well as CMS operational issues, we will delay the implementation of the NOA requirement until CY 2022, and instead will require that HHAs submit a ''no-pay'' RAP for CY 2021. However, for CY 2021, HHAs would be required to submit the ''no-pay'' RAP within five calendar days after the start of each 30-day period of care as this would have been the requirement for the NOA, if the NOA requirement would have been finalized for 2021. Furthermore, in alignment with the proposed NOA process, we will also apply a reduction to home health payment if the ''no-pay'' RAP is not submitted timely. That is, there will be a non-timely submission reduction in payment amount tied to late submission of any ''no-pay'' RAPs when the HHA does not submit the RAP within 5 calendar days from the start of care date for the first 30-day period of care in a 60-day certification period and within 5 calendar days of day 31 for the second 30-day period of care in the 60-day certification period. This reduction in payment amount would be calculated the same way as the NOA non-timely filing policy where the reduction in payment amount would be equal to a 1/30th reduction to the wage-adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submits the ''no-pay'' RAP. We are adopting such changes under a ''good cause'' waiver of proposed rulemaking (see section VII. of this final rule with comment period).

Comment: A number of commenters opposed CMS' proposal to impose a financial penalty on HHAs for failing to submit a timely NOA and instead recommended that CMS consider making the notice of admission a survey requirement in the future. A commenter strongly urged that the NOA submission component be thoroughly vetted with input from providers, EHR vendors, MACs; and another recommended that CMS provide education to assist home health providers with appropriately adapting to all changes.

Response: Currently the RAP establishes an HHA as the primary HHA for the beneficiary during that timeframe and also alerts the claims processing system that a beneficiary is under a home health episode and triggers the consolidated billing edits required by law under section 1842(b)(6)(F) of the Act. Also, under the current structure of the RAP, providers receive an upfront split-percentage payment upon submission of the RAP, providing an incentive for submitting the RAP as early as possible, which also ensures the triggering of the consolidated billing edits. Without a potential payment impact associated with the submission of a NOA, the HHA could submit the NOA when they submit their final claim, which would delay turning on the consolidated billing edits, thus having an adverse effect on other providers providing services to a beneficiary that were likely unaware that the beneficiary was already under a home health episode of care. Therefore, we believe that having a penalty or a reduction in the payment amount for NOAs submitted after the 5 calendar day timely filing requirement is appropriate to aid in expediting the submission of the NOA, triggering consolidated billing edits as soon as possible and reducing claim rejections for other providers who are providing care for a beneficiary who is already under a home health episode. Additionally, our proposal to assess a financial reduction in payment amount for late NOA submission is in alignment with current hospice policy for timely submission of the hospice Notice of Election (NOE). Hospices are paid a bundled per diem payment amount for each day a beneficiary is under a hospice election. If the hospice NOE is not submitted timely (that is, within five calendar dates of the date of 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. We have found the reduction in payment amount for failure to submit an NOE to be an effective tool in ensuring timely NOE submission and believe it would be appropriate to apply a similar policy to home health. As proposed in the CY 2020 HH PPS proposed rule (84 FR 34640), if an HHA failed to submit a timely NOA, the reduction in payment amount would be equal to a 1/30th reduction to the wage-adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the NOA. For example, if an HHA submits their NOA one day late (with an NOA submission 6 days after the start of care), the result would be a 20 percent reduction to the 30-day payment amount. Also, if an HHA submits their NOA 25 days late (with an NOA submission 30 days after the start of care), there would be a 100 percent reduction to the payment The reduction in payment amount (R) to the full 30-day period payment amount would be calculated as follows:

- *Step 1:* The number of calendar days (d) from the start of care until the NOA is submitted divided by 30 days;
- *Step 2:* 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 in payment amount would be $R = (d/30) \times P$.

We proposed that there would be no NOA reduction in payment amount if the NOA is submitted timely (that is, within the first 5 calendar days starting with the start of care date). Likewise, 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 stated 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. This will be an automated process performed by the claims processing system.

We disagree with the commenters' suggestion to make the NOA a survey requirement as the NOA, like the current RAP, serves to identify that the beneficiary is under a home health period of care and trigger consolidated

billing edits and to establish the home health period of care in the Medicare claims processing system. Survey requirements are to ensure health and safety standards in accordance with the home health CoPs; whereas, the NOA serves a claims processing function for payment. Therefore, we believe tying the NOA timely submission requirement to payment is appropriate to mitigate any potential denial/recoupment issues that might occur if other providers file claims for providing services to a beneficiary under a home health period of care before a NOA is submitted.

In the CY 2019 HH PPS proposed rule (83 FR 32390), as well as in this year's CY 2020 HH PPS proposed rule (84 FR 34639), we solicited for comments on the need for HHAs to submit an NOA within 5 calendar days from the start of care to capture that HHA as the primary agency for the beneficiary during their home health episode of care. The comments we received from both the CY 2019 and 2020 HH PPS proposed rules aided in the development of our final NOA policy. We appreciate the careful review of the NOA policy and the feedback we received. Given that the NOA process will be new for HHAs, we will provide education and develop materials for guidance on the NOA policy, including MLN Matters® articles and manual guidance.

Comment: A commenter stated their concerns regarding the how the NOA policy would apply in situations where beneficiaries have a Medicare Advantage Plan but changes coverage to traditional Medicare during open enrollment or when the patient qualifies for a special enrollment while receiving home health services under an existing plan of care.

Response: In this scenario, the HHA would likely fall into one of the established timely filing exceptions for NOAs. To pursue this potential exception, the HHA would file for an exception with their MAC to request a waiver of the timely filing requirement associated with submitting the NOA. If the MAC determines that the circumstance meets the criteria for an exception, the HHA would receive the full 30-day payment amount despite filing the NOA more than 5 calendar days after the start of care.

Comment: Commenters expressed concern regarding all of the changes occurring in CY 2020 with implementation of the PDGM and transitioning to a 30-day unit of payment and these commenters stated HHAs will not have sufficient time to make additional changes to their software systems and business processes to accommodate a NOA process in CY 2021. Commenters questioned whether the Medicare claims processing system would be ready for a NOA process in CY 2021 and cited past issues with the hospice NOE process.

Response: We appreciate commenter concerns about instituting a NOA process in CY 2021 after having to make other system changes to accommodate the PDGM and a 30-day unit of payment in CY 2020. Likewise, we recognize operational issues with the Medicare claims processing system that may make a CY 2021 implementation date overly ambitious. Specifically, because of the way the current claims processing system is developed, any final claim submitted for payment must reconcile to a RAP or the claim will be denied. Because of the changes that would be required to perform this function, we are not able to do a redesign of the claims processing system so that a final claim is processed without matching it to a RAP in time for CY 2021 implementation. Therefore, we will delay implementation of a NOA process until CY 2022 in order to redesign the claims processing system to ensure accurate final claim/RAP matching.

We also agree that we want the home health NOA process to implement in a way where submission errors are minimized. The intent of a NOA process is not to be punitive to providers and we believe that delaying implementation of a NOA process until CY 2022 will allow sufficient time for both HHA and Medicare systems to be modified to accommodate submission of the NOA while mitigating any unintended consequences.

Final Decision: We are finalizing the following policies as they relate to split-percentage payments, Requests for Anticipated Payment (RAPs), and submission of a Notice of Admission (NOA):

For CY 2020:

We are finalizing the proposal to decrease the upfront split-percentage payment for 30-day periods of care beginning on and after January 1, 2020 from 60/50 percent (depending on whether the period of care is the initial or subsequent period) to 20 percent for each 30-day period, for existing HHAs, meaning HHAs certified for participation in Medicare effective on or before December 31, 2018. We remind commenters that in the CY 2019 HH PPS final rule with comment period (83 FR 56463), we finalized a policy that newly-enrolled HHAs (that is, those HHAs certified for participation in Medicare on or after January 1, 2019) will not receive split-percentage payments for periods of care beginning on or after January 1, 2020 and are required to submit a ''no-pay'' RAP for each 30-day period of care.

For CY 2021:

We are finalizing to lower the split-percentage payment to zero for all HHAs (that is, existing HHAs as well as newly-enrolled HHAs who receive no split-percentage payments in CY 2020) and for all 30-day periods of care beginning on or after January 1, 2021. For CY 2021, all HHAs will submit a ''no-pay'' RAP at the beginning of each 30-day period to allow the beneficiary to be claimed in the CWF and also to trigger the consolidated billing edits. This means that existing HHAs (those certified for participation in Medicare on or before December 31, 2018) will have their initial split-percentage payment reduced from 20 percent in CY 2020 to zero percent in CY 2021 for all 30-day periods of care and will submit a ''no-pay'' RAP for all 30-day periods of care in CY 2021. Newly enrolled HHAs (those certified for participation in Medicare on or after January 1, 2019) will continue to submit ''no-pay'' RAPs at the beginning of a 30-day period of care in order to establish the home health period of care, as well as every 30 days thereafter in CY 2021. Therefore, in CY 2021 all HHAs (both existing and newly-enrolled HHAs) will submit a ''no pay'' RAP until RAP elimination and the implementation of the one-time NOA policy in CY 2022.

However, the ''no-pay'' RAP for all HHAs in CY 2021 will require less information before the RAP can be submitted. Since we are removing the upfront payment associated with the RAP, we are relaxing the required information needed to submit the ''no-pay'' RAP. Starting in CY 2021, we are finalizing a policy that the information needed to submit a ''no-pay'' RAP will mirror the NOA policy we are finalizing in this rule. Specifically, we are finalizing a policy that submission of ''no-pay'' RAPs can be made when the following criteria have been met:

(1) The appropriate physician's written or verbal order that sets out the services required for the initial visit has been received and documented as required at §§ 484.60(b) and 409.43(d);

(2) The initial visit within the 60-day certification period must have been made and the individual admitted to home health care.

We are also finalizing a provision which will allow the advance submission of certain RAPs in CY 2021 such that in instances where the plan of care dictates that multiple 30-day periods of care will be required to effectively treat the beneficiary, we will allow the HHA to submit both the RAP for the first 30-day period of care and

the RAP for the second 30-day period of care (for a 60-day certification) at the same time to help further reduce provider administrative burden. Additionally, for CY 2021, we are finalizing a policy where there will be a non-timely submission reduction in payment amount tied to late submission of any ''no-pay'' RAPs when the HHA does not submit the RAP within 5 calendar days from the start of care date for the first 30-day period of care in a 60-day certification period and within 5 calendar days of day 31 for the second 30-day period of care in the 60-day certification period. This reduction in payment amount would be calculated the same way as the NOA non-timely filing policy where the reduction in payment amount would be equal to a 1/30th reduction to the wage-adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submits the ''no-pay'' RAP. We are also finalizing exceptions to the timely filing consequences of the RAP requirements. The RAP timely-filing policies are in alignment with the substance of the timely-filing NOA provisions proposed in the CY 2020 proposed rule (84 FR 34639).

For CY 2022:

Starting in CY 2022, we are finalizing that submission of RAPs will be eliminated and instead we are finalizing the implementation of a one-time NOA submission policy for all HHAs. We are finalizing a policy that all HHAs must submit a NOA to their Medicare contractor within 5 calendar days from the start of care date. The NOA is a one-time submission to establish the home health period of care and covers contiguous 30-day periods of care until the individual is discharged from Medicare home health services. We are also finalizing that NOA submission criteria will require HHAs having a verbal or written order from the physician that contains the services required for the initial visit, and that the HHA has conducted an initial visit at the start of care. We are finalizing that there will be a non-timely submission reduction in payment amount tied to any late submission of NOAs when the HHA does not submit the NOA within 5 calendar days from the start of care. That is, if an HHA failed to submit a timely NOA, the reduction in payment amount would be equal to a 1/30th reduction to the wage-adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the NOA. We are also finalizing exceptions to the timely filing consequences of the NOA requirements. Moreover, we are finalizing the corresponding regulation text changes at § 484.205 to effectuate these split-percentage payment, RAP and NOA policies.

Finally, as we noted in the CY 2020 HH PPS proposed rule, after publication of the CY 2019 HH PPS final rule with comment period, we note that there was an error in titling of the regulations text changes associated with § 484.205(g)(2) when the CY 2019 HH PPS final rule with comment period went to the **Federal Register**. Specifically, paragraph (g)(2)(iii) was incorrectly titled ''Split percentage payments on or after January 1, 2019''. The title of this paragraph implies that split percentage payments are not made to newly-enrolled HHAs beginning on or after January 1, 2019, which is contradictory to the finalized policy on split percentage-payments for newly enrolled HHAs. We finalized a policy in the CY 2019 final rule with comment period that newly-enrolled HHAs will not receive split-percentage payments beginning in CY 2020. As such, in the CY 2020 proposed rule, we proposed to make a correction to the regulations text title to accurately reflect the finalized policy that newly-enrolled HHAs will not receive split-percentage payments beginning in CY 2020. We did not receive any comments on this proposed change. However, because of proposed revisions to split-percentage payments in the CY 2020 proposed rule, the finalized revised title correction, previously at paragraph (g)(2)(iii), has been redesignated to § 484.205(g)(2)(ii). The full revisions to the text at § 484.205 are found in the regulations text section of this final rule with comment period. We are adopting both the revised title change from the CY 2019 HH PPS final rule with comment period and the finalized changes in this final rule with comment period under a ''good cause'' waiver of proposed rulemaking as the final policy mirrors that of the proposed NOA policy.

We note that the regulation at § 484.205(g)(2)(ii), 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 in the February 15, 2019 MLN Matters article: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19005.pdf*.

H. Regulatory Change To Allow Therapist Assistants To Perform Maintenance Therapy

In the CY 2020 HH PPS proposed rule (84 FR 34640) we recognized that, 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. We explained that although Medicare allows for skilled maintenance therapy in a SNF and other outpatient settings, the type of clinician that can provide the therapy services varies 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. We noted that commenters on the CY 2019 Physician Fee Schedule final rule (83 FR 59654) expressed concerns about shortages of therapists. That rule also finalized payment for outpatient therapy services for which payment is made for services that are furnished by a therapist assistant.

Therefore, we stated that 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. We clarified that 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 stated that this would allow home health agencies more latitude in resource utilization, and potentially address the concern regarding therapist shortages in home health. We also noted that allowing assistants to perform maintenance therapy would be consistent with other post-acute care settings, including SNFs. As such, we proposed 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 solicited comments regarding this proposal and welcomed 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 also solicited 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). And finally, we welcomed 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 in addition to any possible effects on the quality of care that could result by allowing therapist assistants to perform maintenance therapy.

The following is a summary of the comments received and our responses to comments on the proposed regulatory change to allow therapist assistants to perform maintenance therapy:

Comment: All commenters were supportive of the proposal to change the regulations at § 409.44(c)(2)(iii)(C) to allow therapist assistants to perform maintenance therapy under the home health benefit. Commenters stated that, as therapist assistants provide skilled professional services in the home, are licensed in practice, and are bound by the same ethical standards as therapists, assistants are qualified to provide maintenance therapy. Additionally, commenters stated that allowing HHAs to utilize therapist assistants within their scope of practice to provide maintenance therapy as well as restorative therapy, will support continued access to therapy services and improve overall quality of care.

Response: We thank commenters for their support of this proposal to allow therapist assistants to practice at the top of their licensure as well as allowing HHAs the flexibility to ensure beneficiary access to all available levels of therapy and resources.

Comment: Several commenters noted that the proposed rule and regulations text referenced ''physical therapist assistants'' and requested clarification regarding whether proposed § 409.44(c)(2)(iii)(C) allows all therapist assistants (physical, occupational, and speech-language pathology) to perform maintenance therapy.

Response: The proposed changes at § 409.44(c)(2)(iii)(C) would allow therapist assistants from all therapy disciplines to perform maintenance therapy within their scope of practice. The reference to physical therapist assistants in the preamble language was an example used to highlight, in general, licensure requirements for therapist assistants. However, the example was in regard to the regulations at § 484.115(g) and (i), which is in reference to the personnel qualifications of both occupational and physical therapist assistants. We thank the commenters for pointing out that the regulations text however, only referenced physical therapist assistants, and note that § 409.44(c)(2)(iii)(C)(*1*) and (*2*) has been changed to ''therapist assistants,'' and not ''physical therapist assistants.'' We thank commenters for their careful review of this proposal and for pointing out this important clarification.

Comment: Commenters provided mixed recommendations regarding the importance of tracking whether a visit is for maintenance or restorative therapy and whether the service is furnished by a qualified therapist or a therapist assistant. A few commenters stated that this data would be relevant to future discussions on changes in intensity/duration of therapy services delivered under the Patient-Driven Groupings Model. Other commenters noted that, as both therapists and therapist assistants are considered ''qualified'' and provide skilled care, it would not be necessary to collect this information. And finally we received a few comments stating that allowing therapist assistants to perform maintenance therapy would not require the supervising therapist to provide more frequent assessments, as this provision would align the requirement with the existing standard in other settings and for restorative therapy under home health.

Response: We thank all commenters for their recommendations and will take all comments under consideration for future rule-making and analysis.

Final Decision: We are finalizing our proposal to allow therapist assistants to perform maintenance therapy under the home health benefit. We are finalizing the proposed regulations text at § 409.44(c)(2)(iii)(C)(*1*) and (*2*) with a modification to reflect that all therapist assistants, rather than only physical therapist assistants, can perform maintenance therapy.

I. 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 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 advance 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 stated in subregulatory guidance in the Medicare Benefit Policy Manual, chapter 7,[27] 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)). Although not legally binding, the revised guidance in the Medicare Benefit Policy Manual is our preferred policy; therefore, in the CY 2020 HH PPS proposed rule, we stated that 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 proposed to change the regulations text at § 409.43(a). Specifically, we proposed 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

[27] Medicare Benefit Policy Manual, Chapter 7—Home Health Services *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

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 § 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 a CoP requirement, we believe that violations for an HHA inadvertently omitting required items are best addressed through the survey process, rather than through claims denials for otherwise eligible periods of care.

We solicited comments on the 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 § 484.60(a) that establish the need for such services.

The following is a summary of the comments received, primarily from HHAs, on the proposed changes to the home health plan of care regulations.

Comment: Commenters overwhelmingly supported the proposal without modifications. In addition, commenters agreed that the individualized plan of care must specify services necessary to meet patient-specific needs, which would be documented in the comprehensive assessment. Commenters also agreed and supported CMS using the survey process to address violations of required missing information or items.

Response: We thank commenters for their support of this proposal. We agree that this may help mitigate any claims denials resulting from these two items missing from the plan of care and 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.

Final Decision: We are finalizing to change the regulations text at § 409.43(a) 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 § 484.60(a) that establish the need for such services. All care provided must be in accordance with the plan of care.

IV. Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624) 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, 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 with comment (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 with comment (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.

As we stated in the CY 2020 HH PPS proposed rule, 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 proposed 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 stated that we were 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*). We further stated that 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.

As discussed in the proposed rule, 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 stated that 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.

We further stated that under our proposal, the data reported would be limited to one year of the Model. We believe this 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 solicited comment on our proposal to publicly report the TPS and TPS 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 also solicited comment on our proposed amendment to § 484.315 to reflect this policy. Specifically, we proposed 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.

The following is a summary of public comments received and our responses:

Comment: The majority of commenters supported our proposal to publicly report these performance data under the HHVBP Model, citing that the data are appropriate for public reporting and, although limited to performance during the final year of the Model, such information would be beneficial for members of the public in the nine states and potentially be valuable to beneficiaries. A commenter encouraged CMS to make additional performance data available beyond our proposal and to provide a link on the Home Health Compare (HHC) website alerting consumers that this supplemental information is available. One commenter advised CMS to provide greater clarity on the TPS and TPS Percentile Ranking, regarding how the data is measured and how it compares

to the star rating data on HHC, by providing guidance to the general public that there will likely be instances where an HHA is a 4 or 5 star agency but not as high of a performer under the HHVBP Model. The commenter expressed concern that the different information available through HHC and the HHVBP Model publicly reported information may confuse the public.

Response: As discussed in the proposed rule, we anticipate making the HHVBP Model performance data available on the HHVBP Model page website at *https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model*. We will take under consideration the commenter's suggestion for also alerting the public of the availability of the Model performance data on the HHC website. In addition, as discussed in the proposed rule, to accompany the data, we will also provide definitions for the HHVBP TPS and the TPS Percentile Ranking methodology, as well as descriptions of the scoring methodology, on the CMS website to ensure the public understands the relevance of these data points and how they were calculated. We will report data by state, CCN, and agency name. As the HHVBP Model performance data is supplemental to the star ratings, we intend to also include a reference to the star ratings available on the CMS website.

Comment: One commenter stated that this information is already available on the HHC website and questioned the utility of reporting this information for only the fifth and final year of the model. Another commenter stated that the information is not easily understood by Medicare beneficiaries or caregivers and is not sufficiently impactful. Furthermore, the commenter stated that the impact of HHVBP, from a fiscal and quality perspective, is not yet fully understood, recent changes in quality metrics for the Model are not yet fully integrated, and more changes are likely needed before HHA-specific results should be publicly displayed.

Response: We continue to believe that publicly reporting HHVBP performance data would incentivize HHAs to improve quality performance under the Model and enhance the current home health public reporting processes to assist consumers, patients, providers, stakeholders and referral sources in making informed choices on their home health care services. We note that the specific information we proposed to publicly report is not currently provided on HHC, and that the HHVBP performance data would supplement the information provided on HHC by together providing a more comprehensive assessment of an HHA's performance across a range of quality measures, including the two new composite measures included in the HHVBP Model's measure set effective performance year 4 (CY 2019). While the publicly reported data would be limited to the final performance year of the model, we believe providing this data would benefit beneficiaries by encouraging participating HHAs to further improve the quality of care they provide.

We agree that it is important to ensure the public can understand the data we publicly report on the HHVBP Model, and as previously discussed, will provide accompanying information with the publicly reported data to promote public understanding. With regard to the recent changes to the Model, in the CY 2019 HH PPS Final Rule, we finalized changes to the quality measures and scoring methodology for the HHVBP Model. We would only be publicly reporting data from the CY 2020 performance year, which will be the second performance year to which these changes in the quality measures and scoring methodology have applied. Prior to publicly reporting the CY 2020 performance data, we will have provided participating HHAs with multiple reports on their performance under the modified methodology. Moreover, as discussed in the proposed rule, 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. Finally, we currently have a publicly available report for PY1 on the evaluation of the HHVBP Model on the CMS Innovation Center website and will have more information forthcoming about the impact of the Model.

Comment: One commenter encouraged CMS to continue to develop and share quality data. However, they also expressed concerns with public reporting, particularly for providers who are not participating in the HHVBP Model, but are located in markets that overlap with HHVBP states. The commenter requested that CMS ensure that the variation of participation by geography does not give advantages or disadvantages to providers based purely on state line because HHAs located in a HHVBP Model state may have more publicly available quality information than HHAs outside of those Model states. The commenter expressed concern that HHAs in non-participating states would not have the same quality information publicly available as the participating HHAs, which could be confusing to consumers and referral sources when selecting an agency.

Response: As stated in our response to the previous commenter's concern, the TPS and TPS Percentile Ranking would supplement the information publicly reported through the HHC star ratings and other public resources, which include information about both HHVBP Model participating and non-participating HHAs and therefore can be used by patients or providers to review quality information on HHAs in non-HHVBP Model states. The HHVBP Model performance data would be publicly reported only for participating HHAs in the nine states that qualified for a payment adjustment percentage based on their Total Performance Score in the fifth and final performance year (CY 2020) of the Model. We believe that making these HHVBP Model performance data available on the CMS Innovation Center's HHVBP Model web page, along with information about what this data represents and how it was calculated, will minimize any potential confusion.

Final Decision: For the reasons stated and after consideration of the comments received, we are finalizing the public reporting of 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 HHVBP Model states that qualified for a payment adjustment for CY 2020. We are also finalizing our proposed amendment to § 484.315 to reflect this policy. As discussed in the proposed rule and in this final rule with comment period, we expect that these data will be made available on the HHVBP Model page of the CMS Innovation Center website 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.

We received several out-of-scope comments, including requests to expand the HHVBP Model and for more information about when we may consider expansion. We thank the commenters for their interest and will address any future changes through rulemaking. We also note that HHVBP Model evaluation reports are currently publicly available on the CMS website (*https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model*), which will be updated with forthcoming reports.

C. Removal of Improvement in Pain Interfering With Activity Measure (NQF #0177)

As discussed in section V.C of this final rule with comment period, after careful consideration of the concerns raised by commenters, the responses provided to those concerns and the discussion of alignment across the QRPs, CMS is finalizing the removal of 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. HHAs will 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. Data for this measure will be publicly reported on HH Compare until April 2020. As we discussed in the CY 2020 HH PPS proposed rule (84 FR 34643), 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. 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 following rules:

- CY 2007 HH PPS final rule (71 FR 65888 through 65891).
- CY 2008 HH PPS final rule (72 FR 49861 through 49864).
- CY 2009 HH PPS update notice (73 FR 65356).
- CY 2010 HH PPS final rule (74 FR 58096 through 58098).
- CY 2011 HH PPS final rule (75 FR 70400 through 70407).
- CY 2012 HH PPS final rule (76 FR 68574).
- CY 2013 HH PPS final rule (77 FR 67092).
- CY 2014 HH PPS final rule (78 FR 72297).
- CY 2015 HH PPS final rule (79 FR 66073 through 66074).
- CY 2016 HH PPS final rule (80 FR 68690 through 68695).
- CY 2017 HH PPS final rule (81 FR 76752).
- CY 2018 HH PPS final rule (82 FR 51711 through 51712).
- CY 2019 HH PPS final rule with comment period (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 with comment (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[28] measures for the CY 2021 program year, as outlined in Table 28.

[28] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

TABLE 28: 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) (NQF #3477)
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. Removal of HH QRP Measures Beginning With the CY 2022 HH QRP

In line with our Meaningful Measures Initiative, in the CY 2020 HH PPS proposed rule (84 FR 34644 through 34645), we proposed to remove one measure from the HH QRP beginning with the CY 2022 HH QRP.

1. Removal of the Improvement in Pain Interfering With Activity Measure (NQF #0177)

We are removing pain-associated quality measures from our quality reporting programs in an effort to mitigate any potential unintended, over-prescription of opioid medications inadvertently driven by these measures. In the CY 2020 HH PPS proposed rule (84 FR 34644 and 34645), we proposed 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.[29]

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,

[29] 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.*

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 proposed 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.

We stated in the proposed rule that if we finalized 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 this measure beginning January 1, 2021. We stated we are unable to remove M1242 earlier due to the timelines associated with implementing changes to OASIS. We also stated that if we finalized this proposal, data for this measure would be publicly reported on HH Compare until April 2020.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Several commenters supported our proposal to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) from the HH QRP as well as the associated OASIS item M1242 used to calculate the measure. One commenter supported removing the measure but recommended that CMS retain M1242 for purposes of risk-adjustment. A few commenters expressed support for CMS' proposal to add new, standardized pain assessment items to the OASIS that would enable the agency to continue collecting data on pain.

Response: We appreciate commenters' support for our proposal to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177) as part of the overall HHS strategy to address opioid misuse. We note that we do not have the authority under the HH QRP to retain the OASIS item M1242 for risk-adjustment purposes once removed from the HH QRP. We will evaluate the SPADE Items in section V.H.3. of this final rule with comment period for risk adjustment use in the future.

Comment: Several commenters requested that CMS develop or share its plans to address pain management in its quality reporting programs (QRPs) in the future after the related measures and data elements are removed, noting that the agency should be consistent in its approach to addressing patient pain. One commenter recommended that CMS track the HHA's approach to appropriate teaching of non-pharmacological pain management options as a part of the individualized care plan.

Response: In the CY 2020 HH PPS proposed rule (84 FR 34672 through 34675) we proposed to add new, standardized patient assessment data elements on pain to the OASIS such that agencies would continue to collect information on patient pain that could support care planning, quality improvement, and potential quality measurement, including risk adjustment. In section V.H.3. of this rule, we have finalized the adoption of the three new pain data elements. We believe their inclusion on the next version of the OASIS will underscore the priority of managing pain. In addition, the CMS Roadmap to Address the Opioid Epidemic includes emphasis on non-pharmacological options for managing pain as critical in the efforts to reduce over-reliance on and misuse of opioids. We are committed to continuing to communicate our strategy for both promoting pain management and appropriate use of opioids.

Comment: The majority of commenters did not support the proposal to remove the Improvement in Pain Interfering with Activity Measure (NQF #0177). Several commenters stated that pain is an important concern for home health patients and that information on pain was valuable to the care team and for quality improvement. These commenters noted that pain can be a root cause of declining health and well-being and is linked to patient quality of life. Some commenters said that measuring pain improvement helps assess treatment efficacy.

Other commenters noted the lack of evidence that measuring pain level in home health is linked to increased opioid use. One commenter additionally noted that generally home health agencies do not prescribe opioids.

While some commenters appreciated CMS' efforts to address the opioid epidemic, they opposed removal of this measure, expressing concern that this removal could decrease the priority of efforts to manage pain, including chronic pain. A few commenters noted that greater emphasis on pain management and impact, as well as promoting and educating providers on non-pharmacological pain management strategies and care plans, were important to addressing opioid misuse.

Response: We appreciate the feedback given by the commenters and acknowledge the concerns raised. We agree that pain is an important concern for home health patients. In response to recommendations from the President's Commission on Combatting Drug Addiction and the Opioid Crisis, to comply with the requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), and to avoid any potential unintended consequences, in the CY 2019 OPPS/ASC final rule (83 FR 59149) we finalized to update the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey measure by removing three recently revised pain communication questions. We proposed the removal of the Improvement in Pain Interfering with Activity Measure (NQF #0177) measure in the spirit of alignment with these efforts.

Additionally, we proposed the removal of this measure to minimize any potential overprescribing of opioids associated with incentives to improve scoring on the measure. We have particular concern with quality measures that assess directly or indirectly whether or not a patient's pain has improved, as we believe such measures may more directly incentivize over-prescribing of opioids. We have addressed this specific issue in previous rule-making. In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38342), we similarly finalized refinements to the HCAHPS Survey measure pain management questions, removing questions such as ''During this hospital stay, how often was your pain well controlled?'' and ''During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?'', to minimize such incentives. We plan to further evaluate this issue across all programs.

Comment: Several commenters expressed concern that removal of M1242 would leave the OASIS without any items to assess pain, noting that pain interference not only captures pain intensity, but also the impact of pain on function.

Response: Given the adoption of the new pain items, in section V.H.3. of this rule the OASIS would continue to contain items that assess pain and the impact on function. CMS will require HHAs to report OASIS M1242 through December 31, 2020. CMS will begin requiring reporting of the new pain items finalized in section V.H.3. of this rule January 1, 2021. This timeline will ensure that there is no gap in the assessment and reporting of pain for this population.

Final Decision: After careful consideration of the concerns raised by commenters, the responses provided to those concerns and the discussion of alignment across the QRPs, we are finalizing our proposal 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. HHAs will 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. Data for this measure will be publicly reported on HH Compare until April 2020.

E. New and Modified HH QRP Quality Measures Beginning With the CY 2022 HH QRP

In the CY 2020 HH PPS proposed rule (84 FR 34645 through 34650), we proposed 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 proposed 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.

In addition to the two measure proposals, we proposed 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. Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure

The 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.[30] 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.[31]

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

[30] Tian, W. ''An all-payer view of hospital discharge to post-acute care,'' May 2016. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp.*

[31] Ibid.

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.[32] [33] [34] [35] [36] [37] Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits, and medication errors.[38] [39] [40] [41] [42] [43] [44] [45] [46] [47] [48] [49]

Communication has been cited as the third most frequent root cause in sentinel events, which The Joint Commission defines [50] 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.[51] When care transitions 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.[52] [53] [54] [55] [56] [57]

Care transitions across health care settings have been characterized as complex, costly, and potentially hazardous, and may increase the risk for multiple adverse outcomes.[58] [59] 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.[60] The communication of health information and patient care preferences is critical to ensuring safe and effective transitions from one health care setting to another.[61] [62]

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.[63] [64] [65] Patients in PAC

[32] 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.

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[38] Barnsteiner, J.H., ''Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,'' The American Journal of Nursing, 2005, Vol. 105(3), pp. 31–36.

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[42] 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.

[43] Mor, V., Intrator, O., Feng, Z., & Grabowski, D.C., '' The revolving door of rehospitalization from skilled nusing facilities'' Health Affairs, 2010, Vol. 29(1), pp. 57–64.

[44] 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.*

[45] 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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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.[66] [67] Preventable adverse drug events (ADEs) may occur after hospital discharge in a variety of settings including PAC.[68] For older patients discharged from the hospital, 80 percent of the medication errors occurring during patient handoffs relate to miscommunication between providers [69] and for those transferring to an HHA, medication errors typically relate to transmission of inaccurate discharge medication lists.[70] 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.[71] [72]

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 [73] and hospital to home.[74] 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.[75]

We would define a reconciled medication list as a list of the current prescribed and over the counter (OTC) medications, nutritional supplements, 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 previous definition 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 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 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,[76] January 27, 2017, and August 3, 2017 [77] 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

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.

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[76] 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.*

[77] 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.*

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 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 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/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 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 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 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 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 measure to the NQF for consideration of endorsement when feasible.

(e) Quality Measure Calculation

The 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 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 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 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 measure, including information about the measure calculation and the standardized items used to calculate this measure, we referred 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 quality measure is the OASIS assessment instrument for HH patients.

For more information about the data submission requirements we proposed for this measure, we refer readers to section V.L.2. of this final rule with comment period.

We invited public comment on this proposal and received one comment specific to this measure. A discussion of this comment, along with our responses, appears below. The remaining comments we received on this measure also addressed the second transfer of health information that we proposed to adopt. Those comments, along with our responses and our final decision concerning both measures, can be found in section V.E.2 of this final rule with comment period.

Comment: One commenter expressed concerns that the proposed Transfer of Health Information to the Provider–Post-Acute Care quality measure denominator does not recognize the importance of transmitting the medication list to providers, such as therapists, that are not included in the proposed definition of ''admitting provider.

Response: We appreciate the suggestion to expand the Transfer of Health Information to The Provider–Post-Acute Care measure to assess the transfer of health information to include other providers such as physical therapists. We recognize the importance of all provider disciplines. Our proposed definition of ''admitting provider'' for purposes of the proposed measure was informed through our measure development and pilot testing process, and it focuses upon providers that can be readily identified through the discharge location item on the OASIS. This would not preclude the sharing of information that will help inform providers such as therapist who may be involved in the patients care once transferred or discharged. At this time, we believe that the current means of provider identification will improve the reliability and validity of the measure.

2. Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure

The 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.[78] 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.[79] [80] [81] [82] [83] Individuals who use PAC care services are particularly vulnerable to adverse health outcomes due to their higher likelihood of having multiple comorbid chronic conditions, polypharmacy, and complicated transitions between care settings.[84] [85] Upon discharge to home, individuals in PAC settings may be faced with numerous medication changes, new medication regimes, and follow-up details.[86] [87] [88] 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.[89] [90]

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.[91] [92] Most PAC EHR systems

[78] 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*.

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[81] 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.

[82] 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.

[83] 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.

[84] 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.

[85] 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.

[86] 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.

[87] 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.

[88] 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.

[89] 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.

[90] 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.

[91] 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/*

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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.[93]

(b) Stakeholder and TEP Input

The measure was developed after consideration of feedback we received from stakeholders, and four TEPs convened by our contractors. Further, the 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,[94] January 27, 2017, and August 3, 2017 [95] 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 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 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-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 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.

Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf.

[92] 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.*

[93] 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.

[94] 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-ssessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-nformation-TEP_Summary_Report_Final-June-2017.pdf.*

[95] 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.*

However, we note that we intend to submit the measure to the NQF for consideration of endorsement when feasible.

(e) Quality Measure Calculation

The calculation of the 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 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 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 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 proposed for this measure, we refer readers to section V.L.2. of this final rule with comment period.

Commenters submitted the following comments on the two proposed transfer of health information measures that we proposed to adopt, beginning with the CY 2022 HH QRP. A discussion of these comments, along with our responses, appears in this section of this final rule with comment period.

Comment: The majority of commenters supported CMS's proposal to adopt the Transfer of Health Information to the Provider-Post-Acute Care quality measure and Transfer of Health to the Patient-Post-Acute Care quality measure beginning with the CY 2022 HH QRP. Many cited the importance of timely and accurate discharge documentation to ensure patient safety.

Response: We appreciate commenters' support for adoption of the Transfer of Health Information quality measures beginning with the CY 2022 QRP. We concur that timely information sharing during the care transfer process is critical to a safe patient transfer.

Comment: Multiple commenters stated that all measures used in the HH QRP should be endorsed by the National Quality Forum.

Response: While section 1899B(e)(2)(A) of the Act requires that any measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, which is currently the National Quality Form (NQF), 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 a consensus organization identified by the Secretary. While these two measures are not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development. As discussed in the CY 2020 HH PPS proposed rule (84 FR 34647 through 34648), there is currently no feasible NQF-endorsed measure that we could adopt under section 1899B(c)(1)(E) of the Act that better addresses the Transfer of Health Information measure domain. We plan to submit the measures for NQF endorsement consideration as soon as feasible.

Comment: A few commenters recommended that we expedite the timeline for beginning the collection of data on these measures. These commenters also recommended that we refrain from making any new revisions to the OASIS, such as adding new items for at least five years if we finalize the proposed changes.

Response:

In the case of the Transfer of Health Information-Provider and Transfer of Health–Patient Post-Acute Care quality measures, the timeline outlined is intended to give providers sufficient time to become familiar with the new measures and participate in trainings and other stakeholder engagement initiatives prior to submitting data on the measures. In response to the request for not making any new revisions, we will take this recommendation under consideration.

Comment: Several commenters expressed concern about anticipated additional burden of collecting the additional assessment data needed to calculate these measures.

Response: We are mindful of burden that may occur from the collection and reporting of data and measures we adopt for our quality reporting programs. The timely and complete transfer of information focuses on the medication list, as recommended by our TEP and through public comment. The transfer of health information measures are each calculated using a single OASIS item and based upon the TEP feedback and pilot test findings, we do not believe that it will be overly burdensome for HHAs to report these items. We also believe that these measures will likely drive improvements in the transfer of medication information between providers and with patients, families, and caregivers and thus justify the additional burden being imposed.

Comment: A few commenters recommended CMS adopt fewer process measures and more outcome measures for the HH QRP.

Response: While we agree that outcome measures are important, and have worked to consistently adopt outcome and claims-based measures, we also believe that process measures, are important and necessary to promote the quality of care furnished by HHAs. The proposed transfer of health measures in particular will ensure care is coordinated at the time of discharge.

Comment: One commenter recommended that the data element for the Transfer of Health Information to the Patient-Post-Acute-Care should be clear that if a Medicare beneficiary has a family caregiver, then that caregiver should receive the list if the beneficiary and family caregiver consent, even if it is also provided to the patient and that the patient, family, or caregiver should be given a chance to ask questions about the medication list to ensure they understand it.

Response: The Transfer of Health Information to the Patient–Post-Acute Care data element asks about the transfer of a reconciled medication list to the patient, family and/or caregiver. We acknowledge the importance of family and/or caregivers and encourage collaboration between the HHA and the family or caregiver when authorized by the patient. HHA staff routinely provide opportunities for family and/or caregivers to identify questions.

Comment: A few commenters requested CMS to clarify what is meant by ''reconciled [medication] list'' and

that the contents of a reconciled medication list are left up to the discretion of the provider.

Response: Suggested elements detailed in the definition are for guidance purposes only and are not a requirement in order to meet the measure criteria. Defining the completeness of the medication list is left to the discretion of the providers and patients who are coordinating this care.

Comment: One commenter questioned the alignment of these proposed measures with the rule ''Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' (CMS–3317–F) and requested CMS ensure alignment of an electronic option to transmit this information that aligns with the requirements in the Discharge Planning final rule.

Response: The final rule, ''Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' (CMS–3317–F) was finalized on September 30, 2019 (84 FR 51836). In the Discharge Planning final rule, we established that effective November 29, 2019 an HHA must establish an effective discharge planning process for each patient when discharged to another PAC setting and establish a standard for the contents of the discharge summary. In addition, we established that an HHA must comply with additional requests from the receiving facility or agency when necessary for the treatment of the patient. We have worked closely with our counterparts in the agency to ensure proper alignment of this policy proposal and the requirements in our Discharge Planning final rule. We would like to note that neither policy contains a requirement for electronic options to transmit the medication list or Discharge planning information electronically. CMS is committed to furthering interoperability in post-acute care and we encourage HHAs that are electronically capturing discharge information to exchange that information electronically with providers who have the capacity to accept it.

Comment: A commenter noted that an HHA may not find out information about a transfer to an inpatient facility until after the fact and may not know to which facility the patient has been transferred.

Response: We acknowledge that there are times when a home health agency may not be notified timely about a transfer to an inpatient facility. This situation would prevent the HHA from being able to transfer the medication information to the new facility. To address this particular concern we have approved a Not Applicable (NA) response at the Transfer to Inpatient Facility time point.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Transfer of Health Information to the Provider–Post-Acute Care (PAC) and Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measures under section 1899B(c)(1)(E) of the Act beginning with the CY 2022 HH QRP as proposed.

3. Update to the Discharge to Community (DTC)–Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) Measure

In the CY 2020 HH PPS proposed rule (84 FR 34650 through 34651), we proposed to update the specifications for the DTC—PAC HH QRP measure (NQF #3477) to exclude baseline nursing facility (NF) residents from the measure. This measure exclusion aligns with the updates to measure exclusions for the DTC–PAC measures that we finalized in the FY 2020 SNF QRP, IRF QRP, and LTHC QRP final rules. The DTC—PAC HH QRP measure (NQF #3477) 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 (NQF #3477) 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 only an Omnibus Budget Reconciliation Act (OBRA) 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, in the CY 2020 HH PPS proposed rule (84 FR 34650 through 34651), we proposed to exclude baseline NF residents from the DTC–PAC HH QRP measure beginning with the CY 2021 HH QRP. We proposed 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 (NQF #3477), including technical information about the proposed exclusion, we refer~~rd~~ 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*.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses, appears in this section of this final rule with comment period.

Comment: The majority of commenters supported CMS' proposal to exclude baseline nursing home residents from the DTC–PAC HH QRP measure (NQF #3477), and expressed appreciation for CMS' responsiveness to stakeholder feedback.

Response: CMS appreciates commenters' support for excluding NF

residents from the DTC–PAC HH QRP measure (NQF #3477).

Comment: MedPAC did not support the proposed exclusion of baseline nursing facility residents from the DTC—PAC HH QRP measure (NQF #3477). They suggested that CMS instead expand their definition of ''return to the community'' to include baseline nursing home residents returning to the nursing home where they live, as this represents their home or community. MedPAC also stated that providers should be held accountable for the quality of care they provide for as much of their Medicare patient population as feasible.

Response: We agree with MedPAC that providers should be held accountable for the quality of care for as much of their Medicare population as feasible. However, we believe this exclusion is necessary to enhance the validity of this measure. For baseline nursing facility residents, the goal of care is successful discharge back to their residence at the nursing facility, which is considered an unsuccessful outcome in this measure, rather than a discharge to the community (defined as home/self-care without HH services). The use of risk adjustment is inappropriate when the measurable outcome of success is not the goal of care for this population.

Community is traditionally understood as representing non-institutional settings by policy makers, providers, and other stakeholders. Including long-term care NF in the definition of community would confuse this long-standing concept of community and would misalign with CMS' definition of community in patient assessment instruments. We conceptualized this measure using the traditional definition of ''community'' and specified the measure as a discharge to community measure, rather than a discharge to baseline residence measure.

Baseline NF residents represent an inherently different patient population with not only a significantly lower likelihood of discharge to community settings, but also a higher likelihood of post-discharge readmissions and death compared with PAC patients who did not live in a NF at baseline. The inherent differences in patient characteristics and PAC processes and goals of care for baseline NF residents and non-NF residents are significant enough that we do not believe risk adjustment using a NF flag would provide adequate control. While we acknowledge that a return to nursing home for baseline NF residents represents a return to their home, this outcome does not align with our measure concept. Thus, we have chosen to exclude baseline NF residents from the measure.

Comment: One commenter noted that the Discharge to Community measure may incentivize inappropriate discharges, adding that the community is not always the best option for some patients. This commenter further noted that this measure could result in agencies not accepting certain types of patients.

Response: We appreciate the importance of incentivizing holistic, patient-specific health decisions and to that end The Discharge to Community measure is risk adjusted based on multiple initial patient characteristics, including diagnoses and previous hospitalizations. This risk adjustment accounts for potentially higher risk of readmission or death and addresses any incentives to not admit or inappropriately discharge high-risk patients.

Final Decision: After consideration of the public comments, we are finalizing our proposal to exclude baseline NF residents from the DTC–PAC HH QRP measure (NQF #3477) beginning with the CY 2021 HH QRP. We are also finalizing our proposal 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.

F. HH QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements Under Consideration for Future Years: Request for Information

In the CY 2020 HH PPS proposed rule (84 FR 34651), we sought 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 29 for future years in the HH QRP.

TABLE 29: 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 are not responding to comment submissions in response to this Request for Information in the CY 2020 HH PPS final rule with comment period, nor are we finalizing any of these measures, measure concepts, and SPADEs under consideration for the HH QRP in this CY 2020 HH PPS final rule with comment period, we appreciate all commenter suggestions and intend to use this input to inform our future measure and SPADE development efforts.

Comment: A number of commenters supported the broad range of measures and data elements suggested as future additions to the OASIS and the HH QRP. One provider stated strong support for CMS's plans to adopt an exchange of health information measure, stressing the need for adoption of interoperable health information technology in PAC settings and in this case in home health. A number of providers supported future adoption of functional improvement outcome measures while a few commenters stressed the value of having maintenance measures focused on patients who are not likely to improve. Another commenter stressed the need for avoiding unintended consequences in punishing HHAs with patients who are expected to decline. A commenter supported the opioid use and frequency quality measure, but stressed the need to ensure that providers aren't penalized for appropriately prescribing medications. Another commenter expressed concern that the adoption of an opioid use and frequency measure may adversely affect the appropriate use of opioids. A few providers suggested a criterion of CMS only including measures in the HH QRP program that have already received NQF endorsement. A few others suggested that CMS strongly pursue removing less useful measures and data elements from the HH QRP at the time in which new measures or data elements are considered for supplementing the HH QRP.

With respect to future SPADE proposals, one commenter strongly supported introduction of a caregiver status data element. A few other commenters suggested the need to add data elements that address housing and food security to any social determinants of health SPADEs under consideration. One commenter stressed the need for current and future SPADEs to more adequately account for patients with a broader range of speech, hearing, and swallowing abilities. Finally, one commenter suggested that CMS should not consider introducing any data element that has not already undergone data testing since this limits the ability of providers and the general public to provide input into potential implementation implications of the data elements.

We appreciate the feedback submitted on these issues.

G. 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 final rule with comment period, and believe that this testing supports their use in our PAC assessment instruments. Therefore, we proposed to adopt many of the same SPADEs that we previously proposed to adopt, along with other SPADEs.

In the CY 2020 HH PPS proposed rule (84 FR 34652), we proposed 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 proposed 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 proposed 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 proposed to use SOC for purposes of admissions because, in the HH setting, the start of care is functionally the same as an admission.

We proposed 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, 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.

We invited public comment on these proposals and received several comments. A discussion of these comments, along with our responses, appears in this section of this final rule with comment period.

Comment: A majority of commenters expressed support for the adoption of the SPADEs within the categories of: Cognitive function and mental status; special services, treatments, and interventions; medical condition and comorbidity data; and impairments. Supporters of the SPADE proposals highlighted the benefit of assessing the areas of SPADEs across post-acute care settings.

Response: CMS thanks the commenters for their support of the goals of standardization and of the proposed SPADEs. We selected the proposed SPADEs in part because of the attributes that the commenters noted.

Comment: Some commenters suggested the need to remove duplicative items in the OASIS and to continually assess the value of the proposed data elements. A number of commenters expressed overall concern with the adoption of the SPADEs due to an anticipated increase in administrative burden for providers. Commenters recommended mitigating this burden through introducing SPADEs over a number of years instead of all at one time. Numerous commenters supported the following recommendations:

1. CMS should issue a draft of the assessment tool no later than 6 months prior to the implementation date, to allow for staff training and other necessary preparations required for agency implementation;

2. CMS should use the authority permitted by the IMPACT Act to waive the Paperwork Reduction Act (PRA) requirements related to modification of the assessment tools for providers subject to the IMPACT Act and expedite CMS's ability to issue a final version of the revised OASIS instrument in a timely manner;

3. CMS should refrain from issuing any revisions to the OASIS instrument for at least 5 years after the 2021 implementation of the proposed changes.

Response: Our development and selection process for the SPADEs prioritized data elements essential to comprehensive patient care. While the introduction of SPADEs will require some additional burden, we maintain that there will be significant benefit associated with each of the SPADEs to providers and patients, in that they are clinically useful (for example, for care planning), they support patient-centered care, and they will promote interoperability and data exchange between providers.

We appreciate the importance of avoiding undue burden and will continue to evaluate and consider any burden the IMPACT Act and the HH QRP places on home health providers. In implementing the IMPACT Act thus far, we have taken into consideration any new burden that our requirements might place on PAC providers. We were also cognizant of the changes that providers will need to make to implement these additions to the OASIS. In CY 2018 HH PPS final rule (82 FR 51732), we provided information about goals, scope, and timeline for implementing SPADEs, as well as updated HHAs about ongoing development and testing of data elements through other public forums. In terms of the timing of the release of the OASIS, we plan to publish a draft of the revised OASIS instrument in early 2020.

Comment: Some commenters suggested that CMS implement the SPADES more slowly than proposed.

Response: We believe the current schedule is appropriate because it aligns with the requirements of the IMPACT Act and because of our efforts to date to prepare for the implementation of new cross-setting SPADES. Our development and selection process for the SPADEs we are adopting in this final rule with comment period reflect prioritized data elements that are essential to comprehensive patient care. We maintain that there will be significant benefit associated with each of the SPADEs to providers and patients, in that they are clinically useful (for example, for care planning), they support patient-centered care, and they will promote interoperability and data exchange between providers. We therefore believe that the proposed implementation timeline for the SPADEs is appropriate.

Comment: One commenter expressed concerns about the methodology of the National Beta Test, noting their belief that the sample was not nationally representative.

Response: The National Beta Test was designed to generate valid and robust national SPADE performance estimates for each of the four PAC provider types. This required acceptable geographic diversity, sufficient sample size, and reasonable coverage of the range of clinical characteristics. To meet these requirements, the National Beta Test was carefully designed so that data could be collected from a wide range of environments (such as geographic regions, and PAC providers of different types, sizes, and ownership), allowing for thorough evaluation of candidate SPADE performance in all PAC settings. The approach included a stratified random sample, to maximize generalizability, and subsequent analyses included extensive checks on the sampling design.

In a document that we issued in conjunction with the proposed rule (entitled ''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*), we described key findings from the National Beta Test related to the proposed SPADEs. We refer readers to an initial volume of the National Beta Test report that details the methodology of the field test (''Development and Evaluation 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*).

Comment: Some commenters recommended that CMS leverage electronic health record initiatives to better utilize SPADEs in home health agencies.

Response: It is our intention to use the SPADE data to inform the common standards and definitions to facilitate interoperable exchange of data. We believe that a core, standardized set of data elements that could be shared across PAC and other provider types is an important first step to foster this interoperability between providers. We are hopeful that by requiring the collection of standardized data, the SPADEs may spur providers, such as home health agencies, to adopt health information technology that eases the burden associated with data collection and data exchange. Further, we believe that the collection of these SPADEs reflect common clinical practice and will improve discharge planning, as well as address errors that can occur during transition from one setting to the next. We note the collection of the SPADEs is one of many tasks to supporting interoperability. We will take into consideration how best to decrease burden from data collection including our manual processes. Additionally, we will take into consideration ways to help incentivize providers to adopt health information technology.

Comment: Some commenters stated support for the proposed SPADEs, but noted reservations that the SPADEs aren't sufficient to address all areas of assessment. One commenter described the SPADEs as an appropriate start, but noted that the SPADEs cannot stand alone, and must be built upon in order to be useful for risk adjustment and quality measurement.

Response: We believe that the SPADEs as proposed represent an important core set of information about clinical status and patient characteristics that may be used for risk adjustment. Additionally, we will continue to assess the use of the SPADES across our PAC settings, including the feasibility, reliability, validity and usability of the data elements in future risk adjustment models and quality measures. We also welcome continued input, recommendations, and feedback from stakeholders about ways to improve assessment and quality measurement for PAC providers, including ways that the SPADEs could be used in the HH QRP. Input can be shared with CMS through our PAC Quality Initiatives email address *PACQualityInitiative@cms.hhs.gov.*

H. 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.[96] 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,[97] and because these assessments provide opportunity for improving quality of care.

Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[98] [99] [100] and promising treatments for severe traumatic brain injury are currently being tested.[101] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[102] [103] [104] [105] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[106]

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;

[96] 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.*

[97] 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.

[98] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

[99] 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.

[100] 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.

[101] 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.

[102] 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.

[103] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[104] 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.

[105] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[106] 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.

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 final rule.

We invited comment on our proposals to collect as standardized patient assessment data the following data with respect to cognitive function and mental status. Commenters submitted the following comments related to the proposed rule's discussion of the cognitive function and mental status data elements.

Comment: A number of commenters supported the proposed use of the BIMS and CAM, but also raised concerns with the lack of sensitivity of these assessments for identifying mild to moderate cognitive impairment that can impact performance of activities of daily living (ADLs).

Response: We acknowledge the limitations of the proposed SPADEs to fully assess all areas of cognition and mental status. We strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. In our past work, we evaluated the potential of several different cognition assessments for use as standardized data elements in PAC settings. We ultimately decided on the data elements in our proposal as a starting point, and we welcome continued input, recommendations, and feedback from stakeholders about additional data elements for standardization, which can be shared with CMS through our PAC Quality Initiatives email address: *PACQualityInitiative@cms.hhs.gov*.

Comment: Another provider recommended supplementing the BIMS and CAM specifically with the Development of Outpatient Therapy Payment Alternatives (DOTPA) items for post-acute assessments. They suggest that DOTPA items, coupled with a functional screen to detect practical problems, need to be administered during PAC assessments.

Response: We evaluated the suitability of the DOTPA, as well as other screening tools that targeted functional cognition, by engaging our TEP, through ''alpha'' feasibility testing, and through soliciting input from stakeholders. At the second TEP meeting in March 2017, members questioned the use of data elements that rely on assessor observation and judgment, such as DOTPA CARE tool items, and favored other assessments of cognition that required patient interview or patient actions. The TEP also discussed performance-based assessment of functional cognition. These are assessments that require patients to respond by completing a simulated task, such as ordering from a menu, or reading medication instructions and simulating the taking of medications, as required by the Performance Assessment of Self-Care Skills (PASS) items. In Alpha 2 feasibility testing, which was conducted between April and July 2017, we included a subset of items from the DOTPA as well as the PASS. Findings of that test identified several limitations of the DOTPA items for use as SPADEs, such as the length of time to administer (5 to 7 minutes). In addition, interrater reliability was highly variable among the DOTPA items, both overall and across settings, with some items showing very low agreement (as low as 0.34) and others showing excellent agreement (as high as 0.81). Similarly, findings of the Alpha 2 feasibility test identified several limitations of the PASS for use as SPADEs. The PASS was relatively time-intensive to administer (also 5 to 7 minutes), many patients in HHAs needed assistance completing the PASS tasks, and missing data were prevalent. Unlike the DOTPA items, interrater reliability was consistently high overall for PASS (ranging from 0.78 to 0.92), but the high reliability was not deemed to outweigh fundamental feasibility concerns related to administration challenges. A summary report for the Alpha 2 feasibility testing titled ''Development and Maintenance of Standardized Cross Setting Patient Assessment Data for Post-Acute Care: Summary Report of Findings from Alpha 2 Pilot Testing'' is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Alpha-2-SPADE-Pilot-Summary-Document.pdf.* While we received support for the DOTPA, PASS, and other assessments of functional cognition, commenters also raised concerns about the reliability of the DOTPA, given that it is based on staff evaluation, and the feasibility of the PASS, given that the simulated medication task requires props, such as a medication bottle with printed label and pill box, which may not be accessible in all settings.

Based on the input from our TEP, results of alpha feasibility testing, and input from stakeholders, we decided to propose the BIMS for standardization at this time due to the body of research literature supporting its feasibility and validity, its relative brevity, and its existing use in the MDS and IRF–PAI.

a. Brief Interview for Mental Status (BIMS)

In the CY 2020 HH PPS proposed rule (84 FR 34653 through 34654), we proposed 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.[107] 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.[108]

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

[107] 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.

[108] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 IRF QRP NPRM. Research Triangle Park, NC. 2016.

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. We stated in the proposed rule that more information about the performance of the BIMS in the National Beta Test could 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 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 proposed 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.

We invited comment on our proposal to collect the BIMS as standardized patient assessment data. We did not receive additional comments specific to the BIMS. General comments on the category of Cognitive Function and Mental Status are discussed in section V.H.1 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the BIMS as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

b. Confusion Assessment Method (CAM)

In the CY 2020 HH PPS proposed rule (84 FR 34654 through 34655), we proposed 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.[109] 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 proposed 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, a 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 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 proposed 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.

We invited comment on our proposals to collect as standardized patient assessment data the following data with respect to the CAM. We did not receive any comments specific to the CAM. General comments on the category of Cognitive Function and Mental Status are discussed in section V.H.1 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the CAM data elements as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

c. Patient Health Questionnaire—2 to 9 (PHQ–2 to 9)

In CY 2020 HH PPS proposed rule (84 FR 34655 through 34656), we proposed 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 in detail in this section of this final rule with comment period.

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

[109] 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.

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.[110] [111] 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 proposed to add the additional data elements of the PHQ–9 to the OASIS to replace M1730, Depression Screening. We are proposed 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,[112] 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 information about the performance of the PHQ–2 to 9 in the National Beta Test can be found in the document titled, ''Final 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 proposed that the PHQ–2 to 9 data elements meet the definition of standardized patient assessment data with respect to

[110] 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.

[111] 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.

[112] 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.

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.

We invited comment on our proposals to collect as standardized patient assessment data the PHQ–2 to 9 data elements. We did not receive comments specific to the PHQ–2 to 9 data elements. General comments on this category of Cognitive Function and Mental Status are discussed in section V.H.1 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the PHQ–2 to 9 data elements as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

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. We did not propose 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 invited comment on our proposals to collect as standardized patient assessment data the following data with respect to special services, treatments, and interventions.

Comment: A number of commenters questioned whether data elements in the SPADE category of Special Services, Treatments, and Interventions were applicable to home health, due to their low prevalence and that these data elements would place an undue burden on providers.

Response: We appreciate the commenters' concern that clinical treatments or response categories documented by some SPADEs are uncommon overall and/or unlikely in the HH setting. We understand that not all SPADEs will be equally relevant to all patients and/or PAC providers. However, we assert that even relatively rare treatments or clinical situations, such as a patient undergoing chemotherapy while receiving PAC services, or having a feeding tube, are important to document, both for care planning within the setting and for transfer of information to the next setting of care. We note that the assessment of many of the less frequently occurring treatments and conditions is formatted as a ''check all that apply'' list, which minimizes burden. When treatments do not apply the assessor need only check one row for ''None of the Above.''

a. Cancer Treatment: Chemotherapy (IV, Oral, Other)

In CY 2020 HH PPS proposed rule (84 FR 34657 through 34658), we proposed 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Chemotherapy (IV, Oral, Other) data element.

Comment: One commenter agreed that it is important to know if a patient is receiving chemotherapy for cancer and the method of administration, but also expressed concern about the lack of an association with a patient outcome. This commenter noted that implications of chemotherapy for patients needing speech-language pathology services include chemotherapy-related cognitive impairment, dysphagia, and speech- and voice-related deficits.

Response: We appreciate the commenter's concern. We agree with the commenter that chemotherapy can create related treatment needs for patients, such as the examples noted by the commenter. However, we believe that it is not feasible for SPADEs to capture all of a patient's needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient's care team.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Chemotherapy (IV, Oral, Other) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

b. Cancer Treatment: Radiation

In CY 2020 HH PPS proposed rule (84 FR 34658), we proposed 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Radiation data element.

Comment: One commenter expressed concern that the radiation data element assesses whether a patient is receiving radiation for cancer treatment, but does not identify the rationale for and outcomes associated with radiation. The commenter noted that implications of radiation for patients needing speech-language pathology services include reduced head and neck range of motion due to radiation or severe fibrosis, scar bands, and reconstructive surgery complications and that these can impact both communication and swallowing abilities.

Response: We appreciate the commenter's concern. We agree with the commenter that radiation can create related treatment needs for patients, such as the examples noted by the commenter. However, we believe that it is not feasible for SPADEs to capture all of a patient's needs related to any given treatment, and we maintain that the Special Services, Treatments, and Interventions SPADEs provide a common foundation of clinical assessment, which can be built on by the individual provider or a patient's care team.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Radiation data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

c. Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System)

In CY 2020 HH PPS proposed rule (84 FR 34658 through 34659), we proposed 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 captures 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, ''Final 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Oxygen Therapy data element. We did not receive any comments specific to the Oxygen Therapy data element. General comments on the category of Special Services, Treatments, and Interventions Data are discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the Oxygen Therapy (Intermittent, Continuous, High-Concentration Oxygen Delivery System) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

d. Respiratory Treatment: Suctioning (Scheduled, As Needed)

In CY 2020 HH PPS proposed rule (84 FR 34659 through 34661), we proposed 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Suctioning data element.

Comment: One commenter requested that respiratory treatment—suctioning data element also assess the frequency of suctioning, as it can impact resource utilization and potential medication changes in the plan of care.

Response: We appreciate the commenter's feedback that the response options for this data element may not fully capture impacts to resource utilization and care plans. The Suctioning data element includes sub-elements to identify if suctioning is performed on a ''Scheduled'' or ''As Needed'' basis, but it does not directly assess the frequency of suctioning by, for example, asking an assessor to specify how often suctioning is scheduled. This data element differentiates between patients who only occasionally need suctioning and patients for whom assessment of suctioning needs is a frequent and routine part of the care (that is, where suctioning is performed on a schedule according to physician instructions). In our work to identify standardized patient assessment data elements, we have strived to balance the scope and level of detail of the data elements against the potential burden placed on patients and providers. We further clarify that any SPADE is intended as a minimum assessment and does not limit the ability of providers to conduct a more comprehensive evaluation of a patient's situation to identify the potential impacts on outcomes that the commenter describes.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Suctioning (Scheduled, As Needed) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

e. Respiratory Treatment: Tracheostomy Care

In CY 2020 HH PPS proposed rule (84 FR 34661), we proposed 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Tracheostomy Care data element.

Comment: A commenter, noted the importance of tracheostomy care and determining whether a patient is receiving tracheostomy care, as it helps with risk adjustment and identifying increased resource utilization. The commenter recommended that the SPADE be expanded to ask about the size of the tracheostomy and whether the tracheostomy has a cuff or is fenestrated.

Response: Risk adjustment determinations is an issue that we continue to evaluate in all of our QRPs, including the HH QRP. We will note this issue for further analysis in our future work to determine how the SPADEs will be used. With regard to the commenter's request to expand the Tracheostomy Care SPADE to include more detail about the type of tracheostomy, we do not believe that this level of clinical detail is necessary to fulfill the purposes of the SPADEs, which are to support care coordination, care planning, and future quality measures. We believe the broad indication that a patient is receiving Tracheostomy Care will be sufficient for the purposes of standardization and quality measurement.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Tracheostomy Care data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

f. Respiratory Treatment: Non-Invasive Mechanical Ventilator (BiPAP, CPAP)

In CY 2020 HH PPS proposed rule (84 FR 34661 through 34662), we proposed 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, ''Final 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, ''Final 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 proposed 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.

We sought comment on our proposal to collect as standardized patient assessment data the Non-Invasive Mechanical Ventilator data element. We did not receive any comments specific to the Non-Invasive Mechanical Ventilator data element. General comments on the category of Special Services, Treatments, and Interventions Data are discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

g. Respiratory Treatment: Invasive Mechanical Ventilator

In CY 2020 HH PPS proposed rule (84 FR 34662 through 34663),we proposed 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.[113]

The proposed data element, Invasive Mechanical Ventilator, consists of a 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, ''Final 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

[113] 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.

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 proposed 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.

We invited comment on our proposals to collect as standardized patient assessment data the Invasive Mechanical Ventilator data element.

Comment: One commenter expressed concern that the invasive mechanical ventilator element only assesses whether or not a patient is on a mechanicalventilator. The commenter suggested CMS consider collecting data to track functional outcomes related to progress towards independence in communication and swallowing.

Response: In our evaluation of the suitability of data elements for SPADEs, we examined the clinical usefulness of candidate SPADEs across the full range of PAC providers, including HHAs. We intend to use the SPADEs to inform care planning and comparing of assessment data for standardized measures. We believe that assessing the use of an invasive mechanical ventilator is a useful point of information to inform care planning and further assessment, such as related to functional outcomes. We wish to clarify that the proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. However, we will take into consideration functional outcomes, overall, that are related to progress towards independence in communication and swallowing in future modifications.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Invasive Mechanical Ventilator data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

h. Intravenous (IV) Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other)

In CY 2020 HH PPS proposed rule (84 FR 34663 through 34664), we proposed 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 proposed 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 proposed 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.

We sought public comment on our proposal to collect as standardized patient assessment data the IV Medications data element. We did not receive any comments specific to the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element. General comments on the category of Special Services, Treatments, and Interventions Data are

discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the IV Medications (Antibiotics, Anticoagulants, Vasoactive Medications, Other) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

i. Transfusions

In CY 2020 HH PPS proposed rule (84 FR 34664 through 34665), we proposed 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 proposed 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.

We invited public comment on our proposal to collect as standardized patient assessment data the Transfusions data element. We did not receive any comments specific to the Transfusions data element. General comments on the category of Special Services, Treatments, and Interventions Data are discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the Transfusions data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

j. Dialysis (Hemodialysis, Peritoneal Dialysis)

In CY 2020 HH PPS proposed rule (84 FR 34655 through 34656), we proposed 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 final rule with comment period, we proposed 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 proposed 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 proposed 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.

We invited public comment on our proposal to collect as standardized patient assessment data the Dialysis data element. We did not receive any comments specific to the Dialysis (Hemodialysis, Peritoneal Dialysis) data element. General comments on the category of Special Services, Treatments, and Interventions Data are discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the Dialysis (Hemodialysis, Peritoneal dialysis) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

k. Intravenous (IV) Access (Peripheral IV, Midline, Central Line)

In CY 2020 HH PPS proposed rule (84 FR 34666 through 34667), we proposed 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 proposed 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 final rule with comment period, 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 proposed 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.

We invited public comment on our proposal to collect as standardized patient assessment data the IV Access data element. We did not receive any comments specific to the IV Access (Peripheral IV, Midline, Central Line) data element. General comments on the category of Special Services, Treatments, and Interventions Data are discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the Intravenous (IV) Access (Peripheral IV, Midline, Central line) data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

l. Nutritional Approach: Parenteral/IV Feeding

In CY 2020 HH PPS proposed rule (84 FR 345667 through 34668), we proposed 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 proposed 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Parenteral/IV Feeding data element.

Comment: One commenter was supportive of collecting the Parenteral/IV Feeding data element, but noted that it should not be a substitute for capturing information related to swallowing which reflects additional patient complexity and resource use.

Response: We agree that the Parenteral/IV Feeding SPADE should not be used as a substitute for an assessment of a patient's swallowing function. The proposed SPADEs are not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. We agree that information related to swallowing can capture patient complexity. However, we also note that Parenteral/IV Feeding data element captures a different construct than an evaluation of swallowing. That is, the Parenteral/IV Feeding data element captures a patient's need to receive calories and nutrients intravenously, while an assessment of swallowing would capture a patient's functional ability to safely consume food/liquids orally for digestion in their gastrointestinal tract.

After careful consideration of the public comment we received on the Parenteral/IV Feeding data element, we are finalizing our proposal to adopt the

Parenteral/IV Feeding data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

m. Nutritional Approach: Feeding Tube

In CY 2020 HH PPS proposed rule (84 FR 34668 through 34669), we proposed 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.[114] 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 proposed 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 proposed in the CY 2020 HH PPS proposed rule (84 FR 34668), 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, ''Final 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-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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Feeding Tube data element.

Comment: In regard to the nutritional approach—feeding tube data element, one commenter noted that in addition to identifying if the patient is on a feeding tube or not, it would be important to assess the patient's progression towards oral feeding within this data element, as this impacts the tube feeding regimen.

Response: We agree that progression to oral feeding is important for care planning and transfer. We wish to clarify that the proposed SPADEs are

[114] 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.

not intended to replace comprehensive clinical evaluation and in no way preclude providers from conducting further patient evaluation or assessments in their settings as they believe are necessary and useful. However, we will take this recommendation into consideration in future work on standardized data elements.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Feeding Tube data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

n. Nutritional Approach: Mechanically Altered Diet

In CY 2020 HH PPS proposed rule (84 FR 34669), we proposed 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.[115]

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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Mechanically Altered Diet data element.

Comment: One commenter was concerned that the Mechanically Altered Diet data element does not capture clinical complexity and does not provide any insight into resource allocation because it only measures whether the patient needs a mechanically altered diet and not, for example, the extent of help a patient needs in consuming his or her meal.

Response: We believe that assessing patients' needs for mechanically altered diets captures one piece of information about resource intensity. That is, patients with this special nutritional requirement may require additional nutritional planning services, special meals, and staff to ensure that meals are prepared and served in the way the patient needs. Additional factors that

[115] 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.

would affect resource allocation, such as those noted by the commenter, are not captured by this data element. We have attempted to balance the scope and level of detail of the data elements against the potential burden placed on providers who must complete the assessment. We will take this suggestion into consideration in future refinement of the clinical SPADEs.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Mechanically Altered Diet data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

o. Nutritional Approach: Therapeutic Diet

In CY 2020 HH PPS proposed rule (84 FR 34670), we proposed 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardize patient assessment data the Therapeutic Diet data element. We did not receive any additional comments specific to the Therapeutic Diet data element. General comments on the category of Special Services, Treatments, and Interventions Data are discussed in section V.H.2 of this final rule with comment period.

Accordingly, we are finalizing our proposal to adopt the Therapeutic Diet data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

p. High-Risk Drug Classes: Use and Indication

In CY 2020 HH PPS proposed rule (84 FR 34670 through 34672), we proposed 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.[116] 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

[116] 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.

medication errors such as drug omissions, errors in dosage, and errors in dosing frequency.[117]

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,[118] while the rate of ADEs in the long-term care setting is approximately 9.80 ADEs per 100 resident-months.[119] In the hospital setting, the incidence has been estimated at 15 ADEs per 100 admissions.[120] 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 from a hospital.[121] [122] [123] 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.[124]

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.[125] We proposed 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; [126] [127] fluid retention, heart failure, and lactic acidosis are associated with hypoglycemics; [128] misuse is associated with opioids;[129] fractures and strokes are associated with antipsychotics; [130] [131] and various adverse events such as central nervous systems effects and gastrointestinal intolerance are associated with antimicrobials,[132] 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.[133] 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.[134]

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.

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[117] 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.

[118] 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.

[119] 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.

[120] 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]

[121] Barnsteiner JH. Medication reconciliation: transfer of medication information across settings-keeping it free from error. *J Infus Nurs.* 2005;28(2 Suppl):31–36.

[122] Rozich J, Roger, R. Medication safety: one organization's approach to the challenge. *Journal of Clinical Outcomes Management.* 2001(8):27–34.

[123] 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.

[124] 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.

[125] Ibid.

[126] 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.

[127] 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.

[128] Hamnvik OP, McMahon GT. Balancing Risk and Benefit with Oral Hypoglycemic Drugs. *The Mount Sinai journal of medicine,* New York. 2009; 76:234–243.

[129] Naples JG, Gellad WF, Hanlon JT. The Role of Opioid Analgesics in Geriatric Pain Management. *Clin Geriatr Med.* 2016;32(4):725–735.

[130] 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].

[131] 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.

[132] Faulkner CM, Cox HL, Williamson JC. Unique aspects of antimicrobial use in older adults. *Clin Infect Dis.* 2005;40(7):997–1004.

[133] 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.

[134] 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.

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,[135] 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 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, ''Final 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the High-Risk Drug Classes: Use and Indication data element.

Comment: One commenter raised the concern of assessing some high risk drug classes, noting that assessing each patient for use of opioids and antipsychotics could discourage appropriate use of these medications in those with advanced illness or receiving palliative care.

Response: We acknowledge commenters' concerns about potential unintended consequences of limiting use of medications for patients with a clinical need. We remain confident that HHAs will continue to focus on appropriate management of pain and mental health issues for all patients as part of their commitment to quality of care and ongoing quality improvement efforts. CMS is also committed to monitor incoming assessment data related to pain for unintended consequences and will be prepared to take necessary steps based on monitoring findings.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the

[135] 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.

High-Risk Drug Classes: Use and Indication data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

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.[136] 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.[137] [138] [139]

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 invited 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 sought comment on whether or not we should add these pain items in light of those concerns. Commenters were asked to address to what extent collection of the data through patient queries might encourage providers to prescribe opioids.

In CY 2020 HH PPS proposed rule (84 FR 34673 through 34675), we proposed 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.[140] 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.[141] 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.[142]

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.[143] 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

[136] 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*

[137] 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*

[138] Fishman SM, Carr DB, Hogans B, et al. Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE). *Pain Med Malden Mass.* 2018;19(3):449–459. doi:10.1093/pm/pnx336.

[139] 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.

[140] 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/.*

[141] 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.*

[142] 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.

[143] National Pain Strategy: A Comprehensive Population-Health Level Strategy for Pain. *https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.*

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 final rule with comment period we have also proposed a SPADE in section V.H.2.p. of this rule that assess for the use of, as well as importantly the indication for the 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.[144] [145] [146] 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.[147] [148] [149]

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, 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,[150] and consistent with HHS's 5-Point Strategy To Combat the Opioid Crisis [151] 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 proposed 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

[144] 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.

[145] Fine, P.G. (2009). Chronic Pain Management in Older Adults: Special Considerations. *Journal of Pain and Symptom Management,* 38(2): S4–S14.

[146] 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.

[147] 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.

[148] 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.*

[149] 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. An*nals of Internal Medicine, 166*(7):493–505.

[150] Society for Post-Acute and Long-Term Care Medicine (AMDA). (2018). Opioids in Nursing Homes: Position Statement. *https://paltc.org/opioids%20in%20nursing%20homes.*

[151] *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html.*

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 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 proposed 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.

We invited comment on our proposal and received the following comments related to our proposal to adopt the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements.

Comment: Some commenters noted specific support for the introduction of the new pain data elements that can assist providers in care planning.

Response: CMS thanks commenters for their support of the pain interference data elements. 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.

Comment: A commenter expressed concerns about the suitability of the Pain Interference data elements for use in patients with cognitive and communication deficits and recommended CMS consider the use of non-verbal means to allow patients to respond to SPADEs related to pain.

Response: We appreciate the commenter's concern surrounding pain assessment with patients with cognitive and communication deficits. The Pain Interference interview SPADEs require that a patient be able to communicate, whether verbally, in writing, or using another method. Assessors may use non-verbal means to administer the questions (for example, providing the questions and response in writing for a patient with severe hearing impairment). Patients who are unable to communicate by any means would not be required to complete the Pain Interference interview SPADEs. In addition, we note that evidence suggests that pain presence can be reliably assessed in non-communicative patients through structural observational protocols. To that end, we tested observational pain presence elements in the National Beta Test, but chose not to propose those data elements as SPADEs at this time. We will take the commenter's concern into consideration as the SPADEs are monitored and refined in the future.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

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.[152]

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 invited comment on our proposals to collect as standardized patient assessment data the Hearing and Vision data elements with respect to impairments.

a. Hearing

In CY 2020 HH PPS proposed rule (84 FR 34675 through 34676), we proposed 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.[153] [154] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life. [155] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[156] [157] [158] higher rates of incident cognitive impairment and cognitive decline,[159] and less time in occupational therapy.[160] 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 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

[152] 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*.

[153] 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.

[154] 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.

[155] 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.

[156] 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.

[157] 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.

[158] 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.

[159] 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.

[160] 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.

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 proposed 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Hearing data element.

Comment: With regard to the hearing data element, one commenter suggested that CMS consider how hearing impairment impacts a patient's ability to respond to the assessment tool in general.

Response: We intend to reinforce assessment tips and item rationale through training, open door forums, and future rulemaking efforts. In the existing guidance manual for the OASIS, we offer tips for administration that direct assessors to take appropriate steps to accommodate sensory and communication impairments when conducting the assessment.

After careful consideration of the public comment we received, we are finalizing our proposal to adopt the Hearing data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

b. Vision

In CY 2020 HH PPS proposed rule (84 FR 34676 through 35677), we proposed 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.[161] [162] [163] [164] [165] [166] [167] 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 proposed 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 proposed 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 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

[161] 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.

[162] 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.

[163] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[164] 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.

[165] 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.

[166] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: The MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[167] 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.

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-ownloads-and-Videos.html*.

Due to the relatively stable nature of vision impairment, we proposed 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 proposed 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.

We invited comment on our proposal to collect as standardized patient assessment data the Vision data element. We did not receive any comments on this category of impairment data or on the Vision data element.

Accordingly, we are finalizing our proposal to adopt the Vision data element as standardized patient assessment data beginning with the CY 2022 HH QRP as proposed.

5. New Category: Social Determinants of Health

a. 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 final rule with comment period) 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 proposed 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 the CY 2020 HH PPS proposed rule (84 FR 34677 through 34684), we proposed 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 final rule with comment period. 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 proposed 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 final rule with comment period.

We also proposed 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 final rule with comment period. 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 final rule with comment period, 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 final, 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.'' [168] 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 proposed 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.[169]

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.[170] 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 suggested a three-pronged strategy to

[168] 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.

[169] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health*. (February 2019).

[170] 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.

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 proposed 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 final rule with comment period, under section 2(d)(2) of the IMPACT Act, would be independent of our proposal discussed in this final rule with comment period in section IV.A.7.f.(2). of the preamble of this final rule with comment period 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 proposed 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 final rule with comment period; (2) Ethnicity, described in section V.G.5.b.(1). of this final rule with comment period; (3) Preferred Language, as described in section V.G.5.(ii).(2). of this final rule with comment period; (4) Interpreter Services, as described in section V.G.5.b.(2). of this final rule with comment period; (5) Health Literacy, as described in section V.G.5.b.(3). of this final rule with comment period; (6) Transportation, as described in section V.G.5.(ii).(4). of this final rule with comment period; and (7) Social Isolation, as described in section V.G.5.b.(5). of this final rule with comment period. 84 FR 34677 through 34684. These data elements are discussed in more detail in section V.G.5. of this final rule with comment period.

Comment: One commenter noted that CMS did not state explicitly in the rule whether it anticipates the SDOH SPADEs will be used in adjusting measures and whether it believes that the IMPACT Act's requirements make it likely the SPADEs will be considered for use in future adjustments. The commenters recommended that CMS be circumspect and transparent in its approaches to incorporating the data elements proposed in payment and quality adjustments, such as by collecting stakeholder feedback before implementing any adjustments.

Response: We thank the commenter for their comment. We intend to use this data to assess the impact that the social determinants of health have on health outcomes. We will continue to work with stakeholders to promote transparency and support providers who serve vulnerable populations, promote high quality care, and refine and further implement SDOH SPADEs. We appreciate the comment on collecting stakeholder feedback before implementing any adjustments to measures based on the SDOH SPADEs. Collection of this data will help us identify potential disparities, conduct analyses, and assess whether any risk adjustments or other type of adjustments are needed. Any future policy development based on this data would be done transparently, and involve solicitation of stakeholder feedback through the notice and comment rulemaking process as appropriate.

Comment: Some commenters stated that the inclusion of the new proposed SPADEs, including SDOH data elements, will be burdensome for providers and agencies to implement. Commenters stated that CMS should explore obtaining this data through Medicare claims. They suggested that the agency should explain why certain data elements can only be obtained through OASIS and other patient assessment tools, rather than through other means, and asked that CMS lay out a multi-year plan for implementation because the current proposal for implementation is not feasible. The commenters suggested that CMS consider reducing the number of SDOH SPADE metrics to ensure questions and overall categories do not create an undue burden and that the new SPADE measures be transitioned by category in a stepwise fashion, allowing achievement of the IMPACT Act requirements while interoperability continues to be strengthened. They also urged CMS to consider a two-year voluntary submission period when additional SPADEs are adopted into the HH QRP to allow for vendor development, facility integration, and staff training, and recommended that CMS provides funding and administrative support for standardizing electronic medical records to ensure effective operability across all post-acute sites.

Response: We thank the commenters for their comments, and we agree that it is important to to minimize burden on providers. Under subsections (A) and (C) of section 2(d)(2, the IMPACT Act requires that CMS periodically 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, as stated above in this section, 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, 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. We will collect this SDOH data under the authority of subsection (B) of section 2(d)(2) to obtain this level of detail. We will provide technical assistance to organizations as they implement these requirements and believe that the implementation timeline we proposed and are finalizing in this rule is sufficient because some of the data elements required may have already been collected by HHAs.

Comment: A few commenters noted concerns that the expanded comprehensive assessment added documentation and that the length of time it will take their clinicians to collect this data would be burdensome. The commenters stated that CMS should not add additional documentation burden to clinicians that add little value to patients or agencies who provide skilled home health services. They stated that CMS should not require agencies to collect SDOH data, which agencies have no ability to address or impact because it only increases time, cost, and frustration for patients and clinicians during the start of care while CMS intends to decrease cash flow during the same period.

Response: We thank the commenters for their comments. We are mindful of the increased obligation that is required though this additional data collection. However, this data collection is highly valuable. 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. 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 use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments.

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. In the CY 2020 HH PPS proposed rule (84 FR 34679) we proposed 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 also proposed 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 proposed 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 proposed 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 proposed 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 final rule with comment period, we proposed 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*.

We solicited comment on these proposals and received the following comments. A discussion of these comments, along with our responses, appears in this section of this final rule with comment period.

Comment: Several commenters supported the inclusion of the seven proposed SDOH data elements, ''race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation'' as data elements collected by HHAs. A commenter noted that this supports the increasing attention on the critical role that social factors place in individual and population health and the growing body of evidence that shows addressing health-related social needs through enhanced clinical-community linkages can improve health outcomes and reduce costs. Another commenter stated that there are gaps in assessing SDOH and they appreciate the considerable

time and energy that CMS has invested to develop these SPADEs.

Response: We thank the commenters for their support, and we agree that collecting SDOH data elements can be useful in identifying and addressing health disparities.

Comment: A few commenters expressed support for moving toward population health and outcomes through the SDOH SPADEs, requested clarification as to what the data will be used for, and inquired whether the data is already collected in other manners.

Response: We thank the commenters for the feedback. We proposed the collection of SDOH SPADEs as part of the requirements outlined in section 1899B(b)(1) of the Act, and more specifically under the category of standardized patient assessment data that we specified under section 1899B(b)(1)(B)(vi) of the Act. SDOH data for home health beneficiaries is not systematically available for home health providers at this time. Collection of this data will enhance patient care, interoperability, and coordinated care. The availability of standardized data through this collection allows for common standards and definitions to be used among the providers, thus ensuring interoperable exchange in longitudinal information between post-acute care providers and other providers. Additionally, standardizing the collection of SDOH SPADES will allow providers to have a better understanding of individual patient's risk factors and treatment preferences, to facilitate better coordinated care and care planning for their patients, and to monitor for improvements in patient outcomes. Further, we are collecting these new SDOH SPADE data elements under the authority of section 2(d)(2) of the IMPACT ACT in order 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.

Comment: Several commenters supported the inclusion of the seven proposed SDOH data elements in the OASIS assessment instrument, as HHAs serve populations affected by social determinants, but recommend including additional factors within the SDOH SPADE category to ensure that the full spectrum of social needs is examined. One commenter suggested evaluating the abilities of the caregiver to support the patient's care needs since any deficit could pose a risk to the health and safety of the patient with advanced illness. A few other commenters suggested that CMS consider adding level of education, food insecurity, and the ability to secure medications to the SDOH assessment. Several commenters stated that collecting sexual orientation and gender identity data alongside the SDOH data elements is important in post-acute care because sexual and gender minorities experience unique cultural and environmental factors, including discrimination and stigma, which can negatively affect access to elder services, health services and health outcomes, and these identities also intersect with the proposed SDOH data elements in unique ways that can create additional barriers to care.

Response: We thank the commenters for the comments and agree that SDOH should include a wide and ever-changing array of elements. In considering which SDOH we proposed to collect, we balanced our policy objective to collect SPADES that will inform care planning and coordination and quality improvement across care settings with the reporting burden for PAC providers. 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, National Academics of Sciences, Engineering, and Medicine (NASEM), Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and ICD–10). We also engaged in discussions with stakeholders. Ultimately, we decided to propose SDOH SPADE data elements, some of which were identified in the 2016 NASEM report, which was commissioned by Office of the Assistant Secretary for Planning and Evaluation (ASPE). We will take the commenters' suggestion to include additional or different SDOH under advisement as we continue to improve and refine the SPADEs.

Comment: One commenter noted that it is unknown what the most useful social risk data to collect is, and that collecting a comprehensive record comes with significant administrative burden. They support transforming general data collection categories into more discrete data points that can be analyzed and aggregated for programmatic strategies. They encouraged CMS to be mindful of meaningful collection and the potential for data overload as well as the ability to leverage existing data sources from across care settings. Since SDOH have impacts far beyond the post-acute care (PAC) setting, they cautioned CMS not to require data collection that cannot be readily gathered, shared or replicated beyond the PAC setting. For healthcare settings that have more established EHRs, the collection of SDOH should be aligned and associated costs for gathering, sharing or replicating considered. They also encouraged CMS to consider leveraging data points from primary care visits and urged CMS to take a holistic view of SDOH across the care continuum so that all care settings may gather, collect or leverage this data efficiently and so that the collection will yield the utmost impact.

Response: We thank the commenter for the comment, and we agree that collecting SDOH data elements can be useful in identifying and addressing health disparities. We also agree with the feedback that we should be mindful of meaningful collection of SDOH data collection efforts so that data elements that are selected are useful. This is one of the reasons why we proposed SDOH SPADE data elements that were identified in the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report, which was commissioned by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Regarding the commenter's suggestion that we consider how it can align existing and future SDOH data elements to minimize burden on providers, we agree that it is important to minimize duplication efforts and align data collection as appropriate and to the extent possible, and will take this under advisement for future consideration. We also intend to solicit on the issue of whether we should collect SDOH data in other health care settings.

(1) Race and Ethnicity

The persistence of racial and ethnic disparities in health and health care is widely documented, including in PAC settings.[171] [172] [173] [174] [175] 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

[171] 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Agency for Healthcare Research and Quality; September 2018. AHRQ Pub. No. 18–0033–EF.

[172] 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.

[173] 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.

[174] 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.

[175] 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.

Disparities Reports, consistently indicates that racial and ethnic disparities persist, even after controlling for factors such as income, geography, and insurance.[176] 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.[177] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[178] 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.[179]

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.[180] 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.*

In the CY 2020 HH PPS proposed rule (84 FR 34680 through 34681), we proposed 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 proposed 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 proposed 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 proposed 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 current race/ethnicity data element included in MDS, LCDS, IRF–PAI, and OASIS.[181] [182] [183] [184] 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.[185] Standardizing self-reported data collection for race and ethnicity allows for the equal comparison of data across multiple healthcare entities.[186] By collecting and

[176] 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.*

[177] National Center for Health Statistics. Health, United States, 2017: With special feature on mortality. Hyattsville, Maryland. 2018.

[178] HHS. Heart disease and African Americans. 2016b. (October 24, 2016). *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[179] 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/.*

[180] ''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.*

[181] 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.

[182] 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.

[183] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[184] ''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.

[185] 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/.*

[186] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for

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 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 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 proposed to adopt the Race and Ethnicity data elements described previously as SPADEs with respect to the proposed Social Determinants of Health category.

Specifically, we proposed 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 proposed 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.

We solicited comment on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Race and Ethnicity SPADEs. A discussion of these comments, along with our responses, appears in this section of this final rule with comment period.

Comment: A few commenters questioned the response options for race. One commenter noted that the response options for race do not align with those used in other government data, such as the U.S. Census or the Office of Management and Budget (OMB). Some of the commenters also stated these responses are not consistent with the recommendations made in the 2009 NAESM (formerly Institute of Medicine) report. One commenter pointed out that the report recommended using broader OMB race categories and granular ethnicities chosen from a national standard set that can be ''rolled up'' into the broader categories. The commenters stated that it is unclear how CMS chose the 14 response options under the race data element and the five options under the ethnicity element and worried that these response options would add to the confusion that already may exist for patients about what terms like ''race'' and ''ethnicity'' mean for the purposes of health care data collection. The commenter also noted that CMS should confer directly with experts in the issue to ensure patient assessments are collecting the right data in the right way before these SDOH SPADEs are finalized. Another commenter noted that the response options for race may not include all races that should be reflected, such as Native African and Middle Eastern. The commenter stated that the item should include ''check all that apply.'' They encouraged CMS to provide rationale for the finalized list of response options. A commenter also urged CMS to review the Race/Ethnicity options to ensure they align with the *www.wh.gov* definitions as they are requirements for the Consolidated-Clinical Document Architecture (C–CDA) and referenced in the US Core Data for Interoperability (USCDI). They pointed out that the SDOH elements will need to align options with the current Consumer Assessment of Healthcare Providers and Systems (CAHPS) requirements and other data reporting requirements, reducing burden for providers to gather this information in multiple locations. The commenter stated that this alignment is imperative to ensure data elements are referenced from a single source of data entry for use across multiple data reporting requirements and that this careful review will help avoid administrative burdens.

Response: We agree that data elements used by CMS should, to the extent possible, cross-reference with those used by other agencies. The proposed race and ethnicity categories align with and are rolled up into the 1997 OMB minimum data standards and conforming with the 2011 HHS Data Standards at *https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status.* The race and ethnicity data element that we proposed also includes ''Check all that apply'' language. As provided in the rationale of the proposed rule (84 FR 34680 through 34681), the 14 race categories and the 5 ethnicity categories conform with the 2011 HHS Data Standards for person-level data collection, which were developed in fulfillment of section 4302 of the Affordable Care Act that required the Secretary of HHS to establish data collection standards for race, ethnicity, sex, primary language, and disability status.

The Section 4302 Standards Workgroup was formed through the HHS Data Council, which is the principal, senior internal Departmental forum and advisory body to the Secretary on health and human services data policy and which coordinates HHS data collection and analysis activities. The Workgroup included representatives from HHS, the OMB, and the Census Bureau. The Workgroup examined current federal data collection standards, adequacy of prior testing, and quality of the data produced in prior surveys; consulted with statistical agencies and programs; reviewed OMB data collection standards and the 2009 Institute of Medicine report *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement;* sought input from national experts; and built on its members' experience with collecting and analyzing demographic data. As a result of this Workgroup, a set of data collection standards were developed, and then published for public comment. This set of data collection standards is referred to as the 2011 HHS Data Standards (*https://aspe.hhs.gov/basic-report/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-and-disability-status*). The categories of race and ethnicity under the 2011 HHS Data Standards allow for more detailed information to be collected and the additional categories under the 2011 HHS Data Standards can be aggregated into the OMB minimum standards set of categories. As noted in the proposed rule, we conducted a listening session regarding the proposed SDOH data elements regarding 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

Health Care Quality Improvement. Washington, DC: The National Academies Press.

included in the 2011 HHS Data Standards to better reflect state and local diversity.

Regarding the commenter who urged CMS to review the proposed race and ethnicity elements to ensure they align with the *www.wh.gov* definitions, we believe the commenter may be referring to the 1997 OMB minimum data standards as the White House's definitions. If so, then as provided earlier in this response, the race and ethnicity categories that were proposed do align with and are rolled up into the 1997 OMB minimum data standards, which also align with CAHPS reporting requirements.

Comment: One commenter stated that the degree of detail required for the social determinants of health sections A1005 ethnicity (focus on Hispanic, Latino/and Spanish origin) and A1010 race may be regarded as intrusive and offensive to patients. This could potentially cause refusal of home care or affect the provider-patient relationship and patient satisfaction.

Response: We thank the commenter for their comment. 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. 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 use, and other measures, as required by section 2(d)(2) of the IMPACT Act, and to assess appropriate adjustments. Moreover, collection of race and ethnicity data, along with the other SDOH data elements, contributes to higher quality patient outcomes due to the ability to use the standardized, interoperable data to facilitate coordinated care and improved patient outcomes. Collection of data for these purposes is authorized under 1899B(a)(1)(B). With the high value of collecting this data in mind, we do acknowledge the commenter's concerns about the potential for patients to view the collection of this data as intrusive and offensive, leading to service refusal or damaging the provide-patient relationship and patient satisfaction. We will monitor the implementation of these new data elements and modify the rule as appropriate.

Providers are required to ask patients for responses to every SPADE data element question required in this rule for the HH QRP, including every SDOH SPADE question. However, patients are not required to respond to any of the SDOH SPADE questions. If the patient declines to or is unable to answer an SDOH SPADE question, the provider must indicate this non-response in the documentation. Therefore, we believe that the patient's wishes and concerns about privacy and whether the question is intrusive are respected and adequately protected under this policy.

(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).[187] Individuals with LEP have been shown to receive worse care and have poorer health outcomes, including higher readmission rates.[188] [189] [190] 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.[191]

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 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

[187] U.S. Census Bureau, 2013–2017 American Community Survey 5-Year Estimates.

[188] 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.

[189] 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.

[190] 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.

[191] IOM (Institute of Medicine). 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

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.[192] 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 proposed 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 ''Final Specifications for HH QRP Measures and SPADEs,'' 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 proposed 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.

Comment: Some commenters noted that preferred language, need for an interpreter, access to transportation, and social isolation are unlikely to change between admission and discharge. One commenter disagrees with CMS's statement in the SNF, IRF and LTCH PPS FY 2020 final rules that ''[patient] circumstances may have changed over the duration of their admission,'' and might change the answers to the health literacy, access to transportation and social isolation items. They acknowledge that for the SNF, IRF, and LTCH QRPs, CMS will allow providers to collect the Language Preference and Interpreter Services at just admission and they felt that CMS should do the same for other SDOH SPADES and just require that they be collected at admission. For example, they noted that Health Literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions, and it is difficult to see how these elemental skills would change over the course of a month-long HH episode. Thus, they encouraged CMS to only require collection of all SDOH SPADEs with respect to admission only.

Response: We thank the commenters for their comments. We agree that Preferred Language and Interpreter Services should just be collected at admission given that a patient's response is unlikely to change. We disagree with the commenters that Health Literacy, Transportation and Social Isolation are unlikely to change from admission to discharge. Unlike the Vision, Hearing, Race, Ethnicity, Preferred Language, and Interpreter Services SPADEs, we believe that the response to this data element is likely to change from admission to discharge for some patients. For example, some patients may develop health issues, such as cognitive decline, during their stay that could impact their response to health literacy thus changing their status at discharge. Cognitive decline can impact a patient's ability to process and understand health information. Similarly, losing a loved one or caregiver, which can happen at any time, could impact someone's response on social isolation and access to transportation. It is common for caregivers to provide emotional support and access to transportation for those for those that they provide caregiving. Therefore, we are finalizing that the Preferred Language and Interpreter Services data elements would just be collected at admission, which will align with the collection of those elements in the IRF, SNF, and LTCH QRPs. We refer the reader to section V.L of this final rule with comment period, where we discuss the collection points for other SDOH SPADEs. For Health Literacy, Transportation, and Social Isolation, we are finalizing that these elements be collected upon admission and discharge, as described in these sections of this final rule with comment period.

(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.'' [193] 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.[194]

Health literacy is prioritized by Healthy People 2020 as an SDOH.[195] 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

[192] 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*.

[193] 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.

[194] 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.

[195] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health*. (February 2019).

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.[196] 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.[197] [198] The S–TOFHLA is a more 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.[199] Furthermore, the S–TOFHLA instrument is proprietary and subject to purchase for individual entities or users.[200] 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 proposed 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.[201] 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.[202] For more information on the proposed Health Literacy data element, we refer readers to the document titled ''Proposed Specifications for HH QRP Measures and SPADEs,'' 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 proposed to adopt the SILS question, described previously for the Health Literacy data element, as SPADE under the Social Determinants of Health category. We proposed to add the Health Literacy data element to the OASIS. We solicited comment on this proposal. A discussion of the comment, along with our response, appears in this of this final rule with comment period.

Comment: One commenter stated that the health literacy question could be improved to capture whether the patient can read, understand, and implement/respond to the information. In addition, the commenter stated that the question does not take into account whether a patient's need for help is due to limited vision, which is different from the purpose of the separate Vision Impairment data element. Another possible question the commenter suggested was ''How often do you have difficulty?'' The commenter suggested that a single construct may not be sufficient for this area, depending on the aspect of health literacy that CMS intends to identify.

Response: We appreciate this commenter's suggestions. We proposed the Single Item Literacy Screener (SILS) to minimize burden and based on stakeholder feedback. We also conducted a listening session regarding the proposed SDOH data elements regarding the importance of collecting health literacy as a component of health care assessments and the listening session stakeholders generally supported the SILS option. Regarding the potential impacts of impaired vision, we do want to note that this rule adopts a vision data element that will be included on the OASIS instrument. The data on a patient's vision will be helpful with the health literacy question to gain a comprehensive picture of the patient's functioning.

(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.[203] Access to

[196] 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.

[197] 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.

[198] Brice, J.H., Foster, M.B., Principe, S., Moss, C., Shofer, F.S., Falk, R.J., Ferris, M.E., DeWalt, D.A. (2013). Single-item or two-item literacy screener to predict the S–TOFHLA among adult hemodialysis patients. Patient Educ Couns. 94(1):71–5.

[199] 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*.

[200] 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*.

[201] 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.

[202] 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.

[203] 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.

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 therefore proposed 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 proposed 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.[204]

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.[205] 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.[206] 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 settings. As such, we proposed 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 ''Final Specifications for HH QRP Measures and SPADEs,'' 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 proposed 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.

We solicited comment on this proposal. A discussion of the comment received, along with our responses appears in this section of this final rule with comment period.

Comment: One commenter supported the collection of data to capture the reason(s) transportation affects a patient's access to health care. The commenter appreciated the inclusion of these items on the HHA and encouraged exploration of quality measures in this area as transportation is an extremely important instrumental activity of daily living to effectively transition to the community.

Response: We thank the commenter for the comment and we will consider this feedback as we continue to improve and refine our quality measures.

(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.[207] [208] Social isolation tends to increase with age, is a risk factor for physical and mental illness, and a predictor of mortality.[209] [210] [211] 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

[204] 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.*

[205] 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.*

[206] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

[207] 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.

[208] 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.*

[209] 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.

[210] 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.

[211] 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.

services and across PAC settings would facilitate the identification of patients who are socially isolated and who may benefit from engagement efforts.

We proposed 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.[212] 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 SPADEs,'' 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 proposed to adopt the Social Isolation data element described previously as SPADE with respect to the proposed Social Determinants of Health category. We proposed to add the Social Isolation data element to the OASIS.

We solicited comment on this proposal. A discussion of the comment, along with our response, appears in this section of this final rule with comment period.

Comment: One commenter stated that the proposed question on social isolation may solicit different answers based on the time horizon considered by the beneficiary as beneficiaries who are newly admitted to an HHA may have experienced differing levels of social isolation throughout their time in acute and post-acute care due to interactions with health care providers, emergency providers, and friends or family visiting due to hospitalization. The commenter believes this question could be improved by adding timeframe to the question. For example, ''How often have you felt lonely or isolated from those around you in the past six months?''.

Response: We thank the commenter for this comment and we will take it under advisement for future consideration. The social isolation question proposed is currently part of the Accountable Health Communities (AHC) Screening Tool. The AHC item was selected from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress. At this time, we do not believe that we should add a time horizon to the social isolation question. During cognitive testing of the proposed social isolation question, there was no evidence of confusion related to the time covered.[213] We will continue to monitor if this is an area that needs further clarification to satisfy the social isolation data element.

After consideration of the public comments, we are finalizing our proposals to collect SDOH data for the purposes of section 2(d)(2) of the IMPACT Act and section 1899B(b)(1)(B)(vi) of the Act as follows. With regard to Race, Ethnicity, Health Literacy, Transportation, and Social Isolation, we are finalizing our proposals as proposed. In response to stakeholder comments, we are finalizing that HHAs that submit the Preferred Language and Interpreter Services SPADEs with respect to admission will be deemed to have submitted with respect to both admission and discharge.

J. 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, in the CY 2020 HH PPS proposed rule (84 FR 34684 through 34685), we proposed to amend 42 CFR chapter IV, subchapter G, by creating a new § 484.245, titled ''Home Health Quality Reporting Program''.

The provisions we proposed to codify were 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) (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.

[212] Northwestern University. (2017). PROMIS Item Bank v. 1.0—Emotional Distress—Anger—Short Form 1.

[213] National Association of Community Health Centers, ''PRAPARE'' available at *http://www.nachc.org/research-and-data/prapare/.*

• 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.

Comment: One commenter supported the proposed codification of the HH QRP requirements.

Response: CMS appreciates the support from the commenter for the codification of the HH QRP requirements.

Comment: One commenter did not support the codification of the HH QRP requirements because of a concern that the current program favors patients whose health status will improve, and does not adequately consider patients whose status will just be maintained by home health services. The commenter believes that codification of the current requirements will reinforce the lack of attention given to appropriate delivery of maintenance nursing and therapy services.

Response: We believe it is important to codify policies that apply to the HHAs as it reflects the policies that apply to HHA's relative to the HH QRP. We do not agree with the recommendation to not codify our policies.

Final Decision: After careful consideration of the public comments received, we are finalizing our proposal to codify requirements for the HH QRP and note that we have made both a substantive change and technical edits.

K. Home Health Care Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey (HHCAHPS)

In the CY 2020 HH PPS proposed rule (84 FR 34685), we proposed 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 proposed to remove the pain question 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 proposed removing this particular pain question is consistent with the proposed removal of pain items from OASIS in section IV.D.1. of this final rule with comment period and is also consistent with the removal of pain items from the Hospital CAHPS Survey. The removal of the pain question 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 welcomed 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.*

We solicited comment on this proposal. A discussion of the comments, along with our responses, appears in this section of this final rule with comment period.

Comment: We received a few comments supporting the removal of Question 10. Commenters supporting the proposal to remove the pain question either did not give a reason, or stated it would reduce burden. Two commenters supported the question's removal due to the unintended consequences of using pain killers.

Response: We thank the commenters for their support.

Comment: The majority of commenters opposed the removal of Question 10. There were a number of reasons that commenters opposed the proposal to remove Q10 from the HHCAHPS survey and, consequently, from the HHCAHPS Specific Care Issues measure. Some commenters stated that pain assessment is a critical component of the home health care patient assessment protocol and should be measured as part of a patient experience of care survey. Several commenters contended that there is no evidence that the discussion of pain is linked to opioid misuse. Commenters wrote that home health providers are unable to prescribe opioids and other medications so there would be no direct impact on opioid prescribing. Some commenters said that because the presence of pain is related to the ability to function, it is important to determine if pain is causing a patient to have limited activity. Other commenters noted that talking about pain is part of the physical therapist's assessment of patients in home health care.

Some commenters thought that Question 10 provides an opportunity to assess if home health agency staff are asking their patients about pain to presumably follow-up with steps to address the patients' pain and discomfort. An example is that a patient with diabetic complications may not feel pain in their feet and by the time they feel pain in a wound in their foot, it is likely that the wound's infection will be in a critical state causing significant discomfort.

Response: We appreciate these comments and agree that monitoring pain is critical in the home health setting to monitor how patients are recovering and to identify emergent issues. Whether the question is on the survey or not, we expect home health agencies to continue to monitor pain in the home health setting.

Final Decision: Based upon the comments received, we have evaluated our proposal to take into consideration points raised by commenters and also concerns raised within HHS. Commenters noted that monitoring of pain is critical and we agree that it is imperative to continue to monitor the management of pain. HHS reviewers also noted that removal of this question would potentially affect the validity of the survey and we also agree with their concern. Therefore, we are not finalizing our proposal to remove Question 10 from all HHCAHPS Surveys.

L. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Background

Section 484.250 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. 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 final rule with comment period, we are finalizing our proposal 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 finalizing our proposal that HHAs would report the data on those measures using the OASIS. In addition, we are also finalizing 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. Schedule for Reporting Standardized Patient Assessment Data Elements Beginning With the CY 2022 HH QRP

As discussed in section V.G. of this final rule with comment period, we finalized to adopt additional SPADEs beginning with the CY 2022 HH QRP. We finalized 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 also finalized that HHAs that submit the Hearing, Vision, Race, Ethnicity, Preferred Language and Interpreter Services 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 consider expanding 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 was proposed but not finalized 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, in the CY 2020 HH PPS proposed rule (84 FR 34598), we sought 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?

We did not propose to expand the reporting of OASIS data used for the HH QRP to include data on all HHA patients regardless of payer. We stated, however, that we welcomed comments on this topic, including comments related to the questions noted previously, and that we would take all recommendations received into consideration.

Comment: Several commenters supported expanding the reporting of OASIS data used for the HH QRP to include data on all patients regardless of their payer in the future. Commenters supporting all-payer collection cited alignment with data collection requirements for other PAC providers, as well as other quality programs, such as the Merit-based Incentive Payment System. Other reasons cited by commenters included more accurate representation of the quality of care furnished by HHAs to the entire HH population, the ability of such data to better guide quality improvement activities, and the reduction of current administrative efforts made by HHAs to ensure that only OASIS data for Medicare and Medicaid patients are reported to CMS. For example, one large HHA noted that OASIS data are already completed for approximately 80 percent

of their patients. A state association commented that a survey of its members found that 52 percent of respondents currently use the OASIS assessment tool for all of their patients, regardless of payer, while 48 percent indicated that they do not.

Several commenters raised the need for explicit authorization to submit data for other payers, and noted this could create additional administrative burden if patient-level affirmation was required. Commenters asked if agencies would need to develop a waiver or consent for information release to be signed by patients covered by payers other than Medicare in order to report their OASIS data to CMS. One commenter recommended that CMS conduct a nationally-representative survey to inform this decision.

The majority of commenters opposed expanding OASIS data reporting to all-payers, most frequently noting the additional administrative burden this would entail. A few commenters noted that the additional data collection was not aligned with the Patients over Paperwork initiative. One commenter specifically raised as an issue the burden of training private-duty nurses on completing the OASIS. Even when data are collected for all patients, some commenters noted that there would be additional costs of submitting those data to CMS.

Several commenters also had concerns that the data collection could implicate HIPAA and questioned how CMS would plan to use these data, which is protected personal health information requested by a government entity that is not the patient's payer. One commenter requested that CMS provide the evidence-basis for expanding OASIS data collection to all payers.

Several commenters noted there was no difference in care provided to patients by payer type. Commenters stated that payer mix varies considerably between agencies, with anywhere from 10 to 50 percent patients being commercially-insured. One commenter noted over fifty percent of their patients are Medicare patients, which they believed is a sufficiently representative sample for quality reporting programs.

Several commenters described differences between commercially-insured patients and Medicare patients, with commenters reporting that commercially-insured patients are usually younger and healthier, and recover more quickly. In addition to the differences in patient demographics, commenters noted that coverage of services tends to differ between Medicare and commercial insurance, and that some commercial insurance providers restrict the number of home health visits in ways that might alter the effectiveness of services for patient outcomes. They also noted that commercial insurers do not have a ''homebound'' requirement for patients and would not likely reimburse the cost of OASIS data collection. Some commenters had concerns on how these differences might adversely affect the quality results and administrative burden.

Response: We appreciate all of the feedback that we received on this issue and we will take it into consideration in our future policy and propose it in future rulemaking whereby HHAs would be required to collect and submit data on HH patients regardless of their payer.

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 drugs, furnished by a qualified home infusion therapy supplier.

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 same items and previously listed 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 with comment period (83 FR 56046), 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).[214] Medicare also makes a separate payment to the physician or 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.[215] The MACs review the Self-Administered Drug (SAD) exclusion lists on a regular basis.[216]

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 home infusion 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.[217] 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

[214] *https://www.govinfo.gov/content/pkg/FR-2012-11-15/pdf/2012-26902.pdf.*

[215] Medicare Benefit Policy Manual, Chapter 15, ''Covered Medical and Other Health Services'', section 50.2—Determining Self-Administration of Drug or Biological. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

[216] Self-Administered Drug (SAD) Exclusion List Report. *www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx.*

[217] Medicare National Coverage Determinations (NCD) Manual. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.html.*

a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act). Section 1861(iii)(3)(C) of the Act defines a ''home infusion drug'' under the home infusion therapy benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a ''qualified home infusion therapy supplier'' as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. The provision specifies qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by 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 other factors such as 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) of the Act, 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 (L33794) 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 with comment period, (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),[218] 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[219] outlining the requirements for the claims processing changes needed to implement this payment.

And last, 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 period (83 FR 56583), we stated that we would carefully monitor the effects of this definition on access to care and that, if warranted and if within the limits of our statutory authority, we would engage in additional rulemaking or guidance regarding this definition. In that same rule, we solicited additional comments on this interpretation and on its effects on access to care.

B. CY 2020 Temporary Transitional Payment Rates for Home Infusion Therapy Services

In the CY 2020 HH PPS proposed rule (84 FR 34689) we discussed section 1834(u)(7) of the Act 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. This temporary payment covers the cost of the 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 found in Tables 55 and 56 in the CY

[218] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=83&Date=05%2f15%2f2019&DocID=L33794&bc=iAAAABAAAAAA&.*

[219] Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020. August 10, 2018. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf.*

2019 HH PPS proposed rule (83 FR 32465 and 32466).[220]

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 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 for 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 payments are found in the August 10, 2018 Change Request 10836, ''Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020.'' [221] Therefore, as proposed, CMS will update the temporary transitional payment amounts based on the CPT code payment amounts in the CY 2020 PFS final rule. At the time of publication of this final rule with comment period, we do not yet have the CY 2020 PFS final rates; however, in accordance with the CY 2020 HH PPS proposed rule, the temporary transitional payments starting on January 1, 2020 will be based on the PFS amounts as specified in section 1834(u)(7)(D) of the Act. We will publish these updated rates in the CY 2020 PFS final rule,[222] and will publish the updated CY 2020 temporary transitional payment rates in the January 2020 DMEPOS fee schedule file.[223] We received a few comments on the proposed rule regarding the CY 2020 temporary transitional payment rates for home infusion therapy. The following are our responses:

Comment: A commenter stated that the lack of defined PFS rates presents a hardship to suppliers when creating budgets for CY 2020. This commenter also suggested that CMS include provisions for geographic adjustments to the temporary transitional payment. The commenter stated that geographic adjustment is necessary in light of nursing shortages noted in several areas of our country, and stated that the shortage of qualified professionals results in costs in recruitment, retention, and wages, and requested that CMS consider these challenges when reviewing the lack of geographic adjustment for the temporary transitional payments.

Response: The proposed CY 2020 PFS rates for the infusion CPT codes can be found at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-P.html.* The final rates will be posted in the CY 2020 PFS final rule, which we expect will be on display by November 1, 2019. The temporary transitional rates for home infusion therapy services will continue to be posted on the DMEPOS fee schedule file, which can be found at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html.* The CY 2020 rates as previously discussed, will be posted by January 1, 2020.

Regarding geographic adjustment, the temporary transitional payment is statutorily limited to the payment methodology as set forth in section 1834(u)(7)(D) of the Act, which states that each payment category is paid at amounts in accordance with the PFS for drugs assigned to such category without geographic adjustment.

Comment: A commenter requested that CMS clarify that nurse practitioners are authorized to establish the home infusion plan of care during the temporary transitional period. The commenter expressed understanding that, as the full payment provisions for the home infusion benefit proposed in this year's rule do not go into effect until CY 2021, there is no statutory requirement that only a physician can establish the plan of care during the transitional payment period.

Response: In the Home Infusion Therapy Services Temporary Transitional Payment Frequently Asked Questions (FAQs), we stated that the eligibility criteria for home infusion therapy services includes the patient being under a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. The FAQs can be found at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf.* The BBA of 2018 gives CMS the authority to implement requirements during the transitional payment period outside of rulemaking. Therefore, we are maintaining our previously-stated requirement that only the physician can establish and review the plan during the transitional payment period.

C. Home Infusion Therapy Services for CY 2021 and Subsequent Years

Upon completion of the temporary transitional payments for home infusion therapy services at the end of CY 2020, we will be implementing the permanent payment system for home infusion therapy services under Section 5012 of the 21st Century Cures Act (Pub. L. 114–255) beginning January 1, 2021. In the CY 2020 HH PPS proposed rule (84 FR 34690), we proposed provisions regarding payment for home infusion therapy services for CY 2021 and beyond in order 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.

We explained that 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, and that these provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services; outline beneficiary qualifications and plan of care requirements; and establish who can bill for payment under the benefit.

Additionally, as previously discussed, in the CY 2019 HH PPS final rule with comment period (83 FR 56583), we solicited additional comments on our interpretation of the definition of ''infusion drug administration calendar day'' and on its potential effects on access to care. Although we did not propose a change to the definition, we received comments on both the CY 2019 HH PPS final rule with comment period and the CY 2020 HH PPS proposed rule with respect to our interpretation.

Of the timely correspondence received in response to the CY 2020 HH PPS proposed rule, approximately 52

[220] CY 2019 HH PPS proposed rule (83 FR 32465 and 32466). *https://www.govinfo.gov/content/pkg/FR-2018-07-12/pdf/2018-14443.pdf.*

[221] CR 10836. Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020. August 10, 2018. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf.*

[222] Medicare Physician Fee Schedule. *https://www.cms.gov/apps/physician-fee-schedule/.*

[223] January 2019 DMEPOS Fee Schedules. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/DME19-A.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

comments pertained to the home infusion therapy benefit. The following is a summary of the proposed rule provisions, comments received, and our responses.

1. Infusion Drug Administration Calendar Day

In general, the comments received on the CY 2019 HH PPS final rule with comment period and the CY 2020 HH PPS proposed rule regarding ''infusion drug administration calendar day'' were similar to those received on the CY 2019 HH PPS proposed rule, and focused primarily on the proposed definition as it pertains to the ''professional services'' covered under the benefit.

Comment: Commenters continued to disagree with the final definition of ''infusion drug administration calendar day,'' and stated that payment for home infusion therapy services should include any day that a home infusion drug is infused, and not just a day on which a professional is in the home furnishing services. Specifically, commenters on the CY 2019 HH PPS final rule with comment period recommended that CMS immediately amend the definition at 42 CFR 486.505 to eliminate the requirement that a skilled professional be in the home in order for reimbursement to occur. The majority of the comments pertaining to the home infusion benefit on the CY 2020 HH PPS proposed rule reiterated this recommendation and called on CMS to revise the existing definition of infusion drug administration calendar day to allow for reimbursement of home infusion services ''each day that an infusion drug physically enters the patient's body, irrespective of whether a skilled professional is in the individual's home.'' Conversely, MedPAC continued to support CMS' definition of infusion drug administration calendar day.

Response: As we stated in the CY 2019 HH PPS final rule with comment period, the definition at 42 CFR 486.505 is consistent with section 1861(iii)(1) of the Act, which defines the term ''home infusion therapy'' as the items and services furnished by a qualified home infusion supplier, which are furnished in the individual's home. Additionally, section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar day in the individual's home, refers to payment only for the date on which professional services (as described in section 1861(iii)(2)(A) of the Act) were furnished to administer such drugs to such individual. In other words, section 1834(u)(7) makes clear that while the single payment covers both professional services under section 1861(iii)(2)(A) and training and education, remote monitoring, and other monitoring services under section 1861(iii)(2)(B), payment is only issued on certain days—days on which professional services are provided in the patient's home.

Comment: Commenters stated that by not defining ''professional services'' and limiting payment to a day on which a skilled professional is in the home, CMS fails to capture a broader cross-section of professional services that do not occur in the patient's home, but that are critical to ensure the safe and effective provision of home infusion therapy services. Several commenters specified that these services include compounding and dispensing of the drug; however, some commenters also identified ''remote pharmacy services'' that they believe should be included in the payment. Commenters on the CY 2020 HH PPS proposed rule elaborated on the notion of ''remote pharmacy services,'' stating that these services include initial and ongoing pharmacist assessments; clinical care planning; drug preparation and compounding; care coordination; medication reconciliation; monitoring, (including remote monitoring) for adverse events and response to therapy; drug therapy evaluation and design; pharmacist interventions and subsequent therapeutic recommendations to prescribers; patient education; and all other associated professional work.

Response: The drugs identified for coverage of home infusion therapy services are paid under the Part B DME benefit. Therefore, the services related to the furnishing of the drug, remote or otherwise, are paid under the DME benefit. Furthermore, a ''qualified home infusion therapy supplier'' as defined in section 1861(iii)(3)(D)(i) of the Act, is not required to furnish services related to the furnishing of the drug. In the CY 2019 HH PPS final rule with comment period CMS stated that we acknowledge that pharmacy services are closely related to the home infusion therapy benefit; however, at this time pharmacy services, furnished by a Medicare-enrolled DMEPOS supplier, associated with the preparation and dispensing of home infusion drugs are covered under the Part B DME benefit and are not part of the specific home infusion therapy benefit (83 FR 56563).

In the CY 2019 HH PPS proposed rule (83 FR 32467) we stated that the DME supplier standards require the DME supplier to document that it or another qualified party has at an appropriate time provided beneficiaries with the necessary information and instructions on how to use Medicare-covered items safely and effectively.[224] Therefore, the professional services covered under the home infusion benefit would include a limited amount of training and education on the provision of home infusion drugs that is not already covered under the DME benefit regarding the appropriate and safe use of the equipment.

In accordance with section 1861(iii)(1)(B), an individual must be under a plan of care established by a physician, prescribing the type, amount, and duration of infusion therapy services, in coordination with the furnishing of home infusion drugs. In order to avoid being overly prescriptive, we did not define ''professional services'' or enumerate a list of services that are covered under the benefit. We did not want to inadvertently omit services which may be necessary for an individual patient or particular therapy or course of treatment, as determined by the physician responsible for the plan of care. As previously discussed and in the CY 2019 proposed rule, the services provided under the home infusion therapy benefit are distinct from those required and paid under the DME benefit (that is, instruction on how to safely and effectively use the DME equipment) and :

- Training and education on care and maintenance of vascular access devices:
++ Hygiene education
++ Instruction on what to do in the event of a dislodgement or occlusion
++ Education on signs and symptoms of infection
++ Teaching and training on flushing and locking the catheter
++ Dressing changes and site care
- Patient assessment and evaluation:
++ Review of patient's history and assessment of current physical and mental status, including obtaining vital signs
++ Assessment of any adverse effects or infusion complications
++ Evaluation of family and caregiver support
++ Review of prescribed treatment and any concurrent oral and/or over-the-counter Treatments
++ Obtaining blood for lab-work
- Medication and disease management education:
++ Instruction on self-monitoring
++ Education on lifestyle and nutritional modifications

[224] *https://www.cms.gov/Medicare/wwwProviderEnrollment-and-Certification/MedicareProviderSupEnroll/wwwdownloads/DMEPOSSupplierStandards.pdf.*

++ Education regarding drug mechanism of action, side effects, interactions with other medications, adverse and infusion-related reactions
++ Education regarding therapy goals and progress
++ Instruction on administering pre-medications and inspection of medication prior to use
++ Education regarding household and contact precautions and/or spills
• Remote monitoring services
• Monitoring services:
++ Communicating with patient regarding changes in condition and treatment plan
++ Monitoring patient response to therapy
++ Assessing compliance

Comment: A few commenters stated that Medicare's interpretation of ''infusion drug administration calendar day'' under the home infusion therapy benefit is inadequate to cover the cost of care, and that consequently, home infusion suppliers would be forced to discontinue home infusion therapy services to Medicare beneficiaries. Some commenters specifically identified subcutaneous immunoglobulin, stating that administration of this biological requires virtually no professional services in the home, and therefore the home infusion supplier would never be reimbursed for the ''pharmacy-based'' services furnished outside of the home. Commenters stated that this would impede access to these services and force patients to receive their infusions in the physician's office, outpatient department, hospital, or nursing home, which are more costly and clinically less appropriate.

Response: The single payment for the home infusion therapy services is only made when a skilled professional is in the patient's home on a day of drug administration. This single payment does not include the DME external infusion pump, supplies (including the home infusion drug), and related services paid under the DME benefit. Medicare payment for an infusion drug administration calendar day is separate from the payment for DME items and services, therefore, a supplier could still be paid for DME items and services under the DME benefit, even if it does not receive payment for home infusion therapy services. Additionally, the home infusion therapy services payment is a single bundled payment amount, set equal to the administration services furnished in a physician's office for each infusion drug administration calendar day, regardless of the actual length of the visit. Therefore, it is unclear why suppliers would limit access to patients requiring ''virtually no services in the home,'' when suppliers are still being paid for the DME, supplies (including the home infusion drug), and services covered under the DME benefit, as well as an additional payment for professional services equal to a set amount of hours, regardless of the actual visit length, when a home visit is furnished.

Comment: A commenter noted anecdotally that since the implementation of the transitional benefit DME suppliers have begun to consolidate or no longer accept new patients under the Part B benefit, and anticipate that more beneficiaries will face access barriers. Commenters requested that CMS make utilization data from 2019 available for public review to allow for a full assessment of how the current policy has impacted access and/or contributed to provider consolidation.

Response: As we stated in the CY 2019 HH PPS final rule with comment period, CMS will monitor home infusion therapy utilization to determine what, if any, effects on access to care occur after implementation of the temporary transitional payments for home infusion therapy. Since the implementation of these payments on January 1, 2019 we have been collecting quarterly data on the number of home infusion therapy users; volume of infusion therapy prescription fills, including by category and individual drugs; and number of DME suppliers furnishing home infusion therapy. We have been monitoring changes in trends between quarters, nationwide trends, and trends across the payment categories and among individual drugs, beneficiary characteristics, and by geographic variation. We have also been monitoring trend data from the past before the implementation of the temporary transitional home infusion therapy payments. Based on the claims data from Q1 2016 to Q4 2018, we found that overall, the utilization of infusion services in Q4 2018 shows a steadily increasing trend across all three care settings (home, outpatient, and physician's office). Specifically, both the numbers of prescription fills and claims for the transitional infusion drugs in the home setting increased steadily in Q4 2018, compared to the previous quarter. Additionally, although there has been fluctuation in the number of DME suppliers supplying transitional home infusion drugs, from Q1 2016 through Q3 2018, the number has increased between Q3 and Q4, indicating that access to services has not been negatively impacted since the drug pricing change from average wholesale price (AWP) to average sales price (ASP) plus 6 percent took effect on January 1, 2017. We will continue to monitor and analyze claims data in order to determine whether, and how access to home infusion therapy services has been impacted since the implementation of the home infusion benefit in CY 2019. We are currently still receiving and analyzing claims data during this time period; however, we note that home infusion utilization for Q1 2019 has been stable and shown slight increases since Q1 2017. We also note that this monitoring and analysis is unrelated to CMS's legal interpretation of the term ''infusion drug administration calendar day.'' We anticipate releasing our analysis of claims data from Q1 2016 through CY 2019 once we have more complete data for CY 2019.

2. Home Infusion Drugs

In the CYs 2019 and 2020 Home Health Prospective Payment System (HH PPS) proposed rules (83 FR 32466 and 84 FR 34690) 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 external infusion pump, supplies (including the home infusion drug), and services covered under the DME benefit. We stated that, 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 (L33794),[225] when such services 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 this LCD for External Infusion Pumps. We also noted that although 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

[225] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://med.noridianmedicare.com/wwwdocuments/2230703/7218263/External+wwwInfusion+Pumps+LCD+and+PA.*

therapy services will be covered beginning in CY 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. As noted in the proposed rule, 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. Therefore, we stated that this means that ''home infusion drugs'' are defined as 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, pursuant to the statutory definition set out at section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act.

Comment: A commenter requested clarification regarding the applicability of payment for services under the home infusion benefit specifically with regard to the administration of intravenous immunoglobulin (IVIG). The commenter noted that we stated in the proposed rule that payment category 1 would include any subsequent intravenous infusion drug additions, and stated that a plain reading of the statutory language indicates that IVIG products would meet the definition of a home infusion drug administered intravenously and thus, would be covered under the home infusion therapy payment beginning in CY 2021. This commenter stated that the proposed codes for home infusion therapy services payment categories, however, do not reflect how IVIG services will be addressed. Similarly, another commenter recommended including IV antibacterial drugs to the list of home infusion drugs eligible for services beginning in CY 2021.

Response: As discussed in the CY 2020 HH PPS proposed rule (84 FR 34690), we stated that Medicare payment for home infusion therapy services is for services furnished in coordination with the furnishing of the intravenous and subcutaneous infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps (L33794), with the exception of insulin pump systems and drugs and biologicals on a self-administered drug exclusion list. In order for the drugs and biologicals to be covered under the Part B DME benefit they must require infusion through an external infusion pump. If the drug or biological can be infused through a disposable pump or by a gravity drip, it does not meet this criterion. IVIG does not require an external infusion pump for administration purposes and therefore, would not be covered under the DME LCD for External Infusion Pumps. We note that a DME external infusion pump is also not covered under the Medicare Intravenous Immune Globulin Demonstration. The Frequently Asked Questions (FAQs) regarding this demonstration state that it is up the supplier to determine the services and supplies appropriate and necessary to administer the IVIG in any given situation, and that this may or may not include the use of a pump.[226] Furthermore, the LCD specifically states that intravenous immune globulin products are not covered under this LCD and specifies that DME coverage of subcutaneous immune globulin (SCIG) applies only to those products that are specifically labeled as subcutaneous administration products. This means that immune globulin labeled for both intravenous and subcutaneous use would not be covered under the LCD.

The reference to payment category 1 including any subsequent intravenous drug or biological additions is in reference to the DME LCD for External Infusion Pumps (L33794). In the CY 2020 HH PPS proposed rule (84 FR 34687) we stated that the DME Medicare Administrative Contractors (MACs) specify the details of which infusion drugs are covered with these pumps through local coverage policies. We also gave examples of covered Part B DME infusion drugs, which we stated currently include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension; immune globulin for primary immune deficiency (PID); insulin; antifungals and antivirals; and chemotherapy, in limited circumstances. As previously discussed, the immune globulin for PID currently covered under the DME LCD for External Infusion Pumps (L33794) is only immune globulin which is administered subcutaneously, not intravenously, and is paid under payment category 2 of the temporary transitional home infusion therapy services payment. If the MACs determine that additional intravenous infusion drugs or biologicals (excluding chemotherapy drugs or other highly complex drugs and biologicals, as those would be paid under payment category 3) meet the criteria to be added to the DME LCD for External Infusion Pumps (L33794), then home infusion therapy services for these newly added intravenous drugs would be covered under payment category 1. Likewise, although there are a few antifungal and antiviral drugs covered under the DME LCD for External Infusion Pumps (L33794), there are currently no antibacterial drugs included and therefore, services for these drugs would not be covered under the home infusion therapy benefit at this time. In general, antibiotics do not require the use of a DME external infusion pump and can be given through an elastomeric pump or by gravity infusion.

Comment: Commenters requested coverage of home infusion therapy services for other drugs and biologicals currently covered under the DME LCD for External Infusion Pumps (L33794). A commenter recommended we cover services for Carbidopa 5 Mg/Levodopa 20 Mg enteral suspension and Hizentra, a subcutaneous immunoglobulin. The commenter noted that the pump and supplies for Carbidopa/Levodopa are billed to DME, similar to immune globulin, and recommended services be covered under payment category 2. Regarding Hizentra, the commenter urged CMS to either extend coverage for services under the home infusion benefit in CY 2021 or remove Hizentra from the self-administered drug exclusion list. Also with regard to the self-administered drug exclusion lists, another commenter encouraged CMS to consider giving additional guidance to the MACs regarding the process and time involved in administering SCIG therapies. Lastly, a commenter recommended identifying all such drugs administered via external infusion pumps covered under the DME benefit as ''home infusion drugs.''

Response: As noted previously, section 1861(iii)(3)(C) of the Act defines a ''home infusion drug'' as a parenteral drug or biological administered *intravenously or subcutaneously.* Although we clarified that a ''home infusion drug'' is a drug or biological included on the DME LCD for External Infusion Pumps (L33794), there are drugs and biologicals on this LCD that do not meet the definition of ''home infusion drug'' required by statute. While Carbidopa/Levodopa is on the DME LCD, because it is an enteral infusion and not administered intravenously or subcutaneously, it does not meet the statutory definition of

[226] *https://innovation.cms.gov/wwwinitiatives/IVIG/supplierfaq.html.*

home infusion drug. Additionally, in the CY 2020 HH PPS proposed rule, we identified additional drugs covered under the temporary transitional payment that would be excluded from the permanent benefit because they, similarly, do not meet the statutory definition of home infusion drug. We stated that Ziconotide and Floxuridine are not considered ''home infusion drugs'' because they are not administered either subcutaneously or intravenously (84 FR 34695). Section 1861(iii)(3)(C) of the Act also excludes insulin pump systems and any drugs or biologicals on self-administered drug exclusion lists from the definition of home infusion drug. Therefore, this provision excludes Hizentra, which is on a self-administered drug exclusion list, from the benefit beginning in CY 2021. Because this is a statutory exclusion, CMS does not have the authority to extend coverage under the home infusion benefit for services related to drugs and biologicals on these lists. In the CY 2020 HH PPS proposed rule we discuss that the determination for which drugs and biologicals belong on a self-administered drug exclusion list is made on a drug by drug basis, taking into account whether a drug is self-administered by more than 50 percent of Medicare beneficiaries (84 FR 34687). Chapter 15, section 50.2 of the Medicare Benefit Policy Manual [227] addresses the specific policy for making this determination in general, therefore, further guidance to the MACs regarding specific therapies is unnecessary.

Comment: Many commenters expressed concern that relying on the DME LCD for External Infusion Pumps limits the ability for new and/or innovative drugs to be added under the home infusion therapy benefit. Commenters indicated that the LCD process and the DME criteria is such that the DME MACs continue to evaluate drugs based on the notion that only drugs that patients can self-administer, or that a caregiver can administer for the patient, can be added. Commenters recommended that CMS require the DME MACs to increase transparency of their coverage policy by further detailing the criteria used to make coverage determinations and ensuring that coverage determinations follow current clinical practice guidelines and patient need. Another commenter urged CMS to clarify that Medicare covers the cost of pump maintenance for the duration of the drug's use in treating the beneficiary and further clarify that pumps supplied per the benefit remain the property of the pharmacy and are returnable when the beneficiary ceases service.

Response: As detailed in section VI.C.1.a. of the CY 2020 HH PPS proposed rule, home infusion drugs are those drugs and biologicals identified on the DME LCD for External Infusion Pumps (L33794). This does not however, limit the scope of drugs to only those drugs and biologicals which are currently on this LCD at this time. Table 30 lists the drugs and biologicals which are currently on the DME LCD for External Infusion Pumps (L33794), and which also meet the definition of a home infusion drug; however, it is important to note that this list is not static. The DME criteria used to determine which items are included on the LCD for External Infusion Pumps, as well as the cost of pump maintenance, is out of the scope of this final rule with comment period, which focuses on the home infusion therapy benefit. However, in response to stakeholder concerns regarding the limitations of the DME LCDs for External Infusion Pumps that preclude coverage to certain infused drugs, we are soliciting comments on the criteria CMS could consider to allow coverage of additional drugs under the DME benefit.

With regard to transparency in the LCD Development Process, the 21st Century Cures Act required a summary of the evidence and a publication of a written explanation of the rationale to be included in the LCD. The new LCD development process that includes these procedures is outlined in Chapter 13 of the Medicare Program Integrity Manual (PIM); pub. 100–08 (found at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html*) and went into effect on January 1, 2019. Therefore, the new LCD development requirements do not apply to local coverage policies prior to the effective date of January 1, 2019.

In addition, the mechanism that allows the Medicare Administrative Contractors (MACs) to change coverage continues to be the LCD reconsideration process. The LCD reconsideration process allows any stakeholder to submit new evidence to ask for a reconsideration of the policy. The full LCD reconsideration process and requirements are also located at Chapter 13 of the PIM. We encourage stakeholders with additional evidence to engage their MAC in consultation regarding the available evidence that was not considered in the initial review, or to sensitize the MAC of emerging evidence that could be useful in an upcoming reconsideration once published.

3. 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, we proposed to make a number of revisions to the regulations to implement the home infusion therapy services payment system beginning on January 1, 2021. We proposed 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 proposed 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 proposed at § 414.1510 that, as a condition for payment, qualified home infusion therapy suppliers must 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 proposed 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 proposed 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 proposed to require at § 414.1515, that

[227] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

the plan of care must contain those items listed in § 486.520(b). We also stated that 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. The following is a summary of the comments received on the proposed conditions for payment, which include patient eligibility and plan of care requirements, and our responses.

Comment: A commenter stated that proposed § 414.1515(c) does not provide applicable providers the authority to properly manage home infusion patients under their care. The commenter noted that while the statute says that a physician is required to establish and periodically review the plan of care, the patient can be under the care of an applicable provider, which does not have to be a physician. Commenters disagreed with the portion of proposed § 414.1515(c) which states that a physician must sign and date the plan of care upon any changes to the plan of care, and stated that this is not required by statute and prevents an applicable provider from managing a patient under his/her care when the applicable provider is not the ordering physician. This commenter requested that CMS remove this language from proposed § 414.1515 or amend the language to state that the ''ordering physician or applicable provider must sign and date the plan of care upon any changes to the plan of care.''

Response: We appreciate the commenter's review of the regulatory language and recognition that in accordance with section 1861(iii)(1)(A) of the Act, the patient must be under the care of an applicable provider, which as defined in 1861(iii)(3)(A) of the Act, is a physician, nurse practitioner, or physician assistant. Additionally, section 1861(iii)(1)(B) of the Act, states that the beneficiary must be under a plan of care, established by a physician (defined at section 1861(r)(1) of the Act). Therefore, for payment purposes, the plan of care must be established and reviewed by a physician. This means that all services billed to Medicare have to be reflected in the plan of care, which is required to be established and reviewed by the physician, which includes any changes or updates to the plan, as stated in the regulatory language. We will consider whether an applicable provider can update the plan of care for future rulemaking.

Comment: Several commenters recommended that CMS adopt a timeframe for the physician review of the plan of care. Some commenters specifically recommended that CMS require the physician to review the plan of care at least every 90 days.

Response: As section 1861(iii)(1)(B) of the Act states that the plan of care must be periodically reviewed by a physician in coordination with the furnishing of home infusion drugs, we believe this to mean that the home infusion plan of care must be established and reviewed by the physician, in consultation with the DME supplier responsible for furnishing the home infusion drugs. Additionally, the DME Quality Standards require suppliers to work collaboratively with the physician prescribing the drug, who is ultimately responsible for any changes in type, dosage, and frequency of medication. Therefore, as coordination is required between the entity responsible for furnishing the drug, and both the entities (if they are not the same entity) responsible for ordering the home infusion therapy services and the home infusion drug, we would expect all entities to be involved in the care coordination process.

However, we do recognize the integral part the plan of care plays in care coordination between providers, particularly when the physician ordering the home infusion drug is not the same physician establishing the home infusion therapy plan of care. Coordination between the physician ordering the home infusion drug, the physician ordering the home infusion services, and the DME supplier furnishing the home infusion drug is imperative in providing safe and effective home infusion therapy. Coordination would likely include review of the patient assessment and evaluation, including interpretation of lab results as they pertain to changes in medication type, dose, or frequency. And, as many of the home infusion drugs and biologicals likely require weekly bloodwork and close monitoring, a current home infusion therapy plan of care is essential in order to ensure that the qualified home infusion therapy supplier is providing the appropriate professional services, including patient monitoring, to ensure that administration is safe and effective. Additionally, these drugs and biologicals treat a variety of both acute and chronic conditions. Treatment regimens and schedules will likely vary in length and intensity depending on the drug, individual response to therapy, and disease progression. As such, patient needs, including interventions and monitoring, will likely fluctuate based on short-term and long-term goals of the varying treatment regimens. For this reason, in order to ensure that therapy is safe and effective throughout the course of treatment, the physician responsible for the home infusion therapy plan of care should review the plan on a regular basis, in coordination with the DME supplier.

We received comments on the proposed health and safety standards in the CY 2019 HH PPS proposed rule stating that establishing timeframe requirements could conflict with State laws, creating duplicative requirements, which may add burden to home infusion therapy suppliers. Therefore, we stated in the CY 2019 HH PPS final rule with comment period that we would not include specific timeframes for the review of the plan of care, and will defer to existing State laws and regulations (83 FR 56563). However, we will take the recommendations received on the CY 2020 HH PPS proposed rule regarding establishing a timeframe for physician review under consideration for future rulemaking.

Comment: Several commenters recommended that CMS require that home infusion suppliers document the following in the plan of care: Drug name, strength, and dosage; frequency of administration; route of administration; method of administration; and a care plan for the following professional services: Patient assessments; drug therapy evaluation and design; drug preparation and compounding; care coordination; monitoring and remote monitoring; and nursing services.

Response: The CY 2019 HH PPS final rule with comment period finalized the plan of care requirements for home infusion therapy suppliers. Section 486.520(b) requires that the home infusion therapy supplier 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 would also include the specific medication, including the prescribed dosage and frequency, as well as the professional services to be utilized for treatment. In addition, the plan of care would specify the care and services necessary to meet the patient-specific needs (83 FR 56562). Additionally, proposed § 414.1515 requires, as a condition for payment, that in addition to the elements indicated in § 486.520(b), 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. These required elements

capture the majority of the commenters' recommendations; however, any additional regulatory plan of care elements would be required to go through notice and comment rulemaking.

Comment: Several commenters recommended that CMS add a requirement that the same physician be responsible for signing the DME detailed written order (DWO) and the home infusion therapy plan of care. Commenters stated that because CMS is proposing to allow the DME supplier and the home infusion therapy supplier to be different entities, there is a risk for medication errors resulting from conflicting orders being obtained by the individual providers involved in the patient's care.

Response: We recognize the commenter's concern; however, the statute does not specify that the home infusion plan of care must be established by the same physician who orders the DME and signs the DWO. While we would expect that in most cases the physician ordering the home infusion therapy services is the same physician ordering the DME and the infusion drug, we recognize that this may not always be the case. However, § 486.520(a) requires that in addition to the professional services utilized for treatment, the home infusion plan of care must include the specific home infusion drug or biological, along with the prescribed dosage and frequency of the medication. Therefore, regardless of whether the physician ordering the home infusion drug is the same physician ordering the home infusion therapy services, there must be care coordination between both entities in order to meet the plan of care requirements under § 486.520(a).

Comment: A commenter noted that in the CY 2019 HH PPS final rule with comment period, CMS finalized the definition of ''applicable provider'' at § 486.505 as ''a physician, a nurse practitioner, and a physician assistant;'' however, the regulatory language under 42 CFR 486.505 uses the term ''nurse provider'' rather than ''nurse practitioner.'' The commenter therefore, requested a technical edit of 42 CFR 486.505 to change the language to read ''nurse practitioner'' in accordance with the statutory definition at 1861(iii)(3)(A) of the Act.

Response: We thank the commenter for his/her review of the regulatory language and agree that the language at § 486.505 should be changed from ''nurse provider'' to ''nurse practitioner'' and will be modified accordingly.

Final Decision: We are finalizing, as proposed, the home infusion therapy services conditions for payment at 42 CFR part 414, subpart P.

In addition, in response to the comment made regarding terminology, we will amend the regulations at § 486.505 to change the term ''nurse provider'' to ''nurse practitioner.'' We are also amending § 414.1550(a)(1) and (2) to include ''or service.'' Although these changes were not proposed in the proposed rule, we are adopting the changes here under a ''good cause'' waiver of proposed rulemaking. The specific changes we are making in the regulations are simply technical corrections in the language and do not reflect any additional substantive changes. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into this final rule with comment period is unnecessary and contrary to the public interest.

4. 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. Importantly, neither the statute, nor the health and safety standards and accreditation requirements, outlined in 42 CFR part 486, require the qualified home infusion therapy supplier to furnish the pump, home infusion drug, or related pharmacy services. Therefore, in the CY 2020 HH PPS proposed rule, we noted that the infusion pump, drug, and other supplies, and the services required to furnish these items (that is, the compounding and dispensing of the drug) remain covered under the DME benefit.

We stated in the CY 2020 HH PPS proposed rule that we did not specifically enumerate a list of ''professional services'' for which the qualified home infusion therapy supplier is responsible 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 (84 FR 34692). However, we noted 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 statute. We stated that this means that 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, payment for these services is built into the bundled payment for an infusion drug administration calendar day.

Comment: A commenter supported CMS' efforts to promote supplier participation in Medicare home infusion therapy services and improve access for beneficiaries by giving them more choices of providers under the benefit.

Response: We thank the commenter for this recognition and also anticipate that the breadth of providers able to become accredited as qualified home infusion therapy suppliers will help ensure continued access to home infusion services.

Comment: A commenter referenced the discussion of billing for chronic care management and remote patient monitoring codes associated with the home infusion benefit. The commenter indicated that CMS only references ordering physicians and does not mention applicable providers, and stated that CMS should clarify that these codes, and other care coordination services, are billable by the applicable provider managing the patient's care. Another commenter suggested adding teaching and training users to self-administer using a pump, troubleshooting pump issues (for example, telephonically or via video monitoring); and providing clinical/quality assessments such as monitoring the efficacy of drugs (for example, number of infections for a user of immune globulin diagnosed with primary immunodeficiency (PID)) to the proposed list of remote monitoring services.

Response: The discussion referencing the PFS chronic care management and remote monitoring codes was regarding the services for which a provider can bill separately under the PFS and was referenced in order to separate these services from the care coordination included in the bundled services under the single unit of payment for home

infusion therapy suppliers. These are not codes for which home infusion therapy suppliers can bill separately under the home infusion therapy benefit, therefore, which providers can bill for these codes is out of the scope of the CY 2020 HH PPS final rule with comment period.

Additionally, as we did not propose a list of remote monitoring services considered professional services under the home infusion therapy benefit, it is unclear if the comment regarding teaching and training on the pump pertains specifically to the CY 2020 HH PPS proposed rule. However, we will note that the commenter's suggestion that the infusion therapy supplier engage in training and education on the item of DME, address services already covered under the DME benefit, and would not be covered under the home infusion therapy benefit. Additionally, in the CY 2019 HH PPS proposed rule, although we did not define home infusion therapy professional services, we did give examples of services we believe fall under the home infusion therapy benefit. Clinical assessments, including monitoring efficacy of drug therapy, was included in these examples (83 FR 32468).

Comment: Several commenters expressed concern about care coordination between different entities providing services under various benefits. These commenters stated that the proposed rule tasked the home infusion therapy supplier with furnishing the necessary services to administer the drug in the home, but does not require the qualified home infusion therapy supplier to furnish the pump, home infusion drug, or related pharmacy services. Commenters stated that because ''CMS' interpretation'' allows the DME supplier and the home infusion therapy supplier to be separate entities, this could potentially create confusion about roles and responsibilities. Further, commenters indicated that CMS makes no requirement for the provider of HIT services to coordinate directly with the DME supplier. A commenter stated that typically, commercial payers structure the home infusion benefit as a pharmacy-coordinated service, where the pharmacy assumes responsibility for case managing the therapy and provides oversight of all the professional services. The commenter noted that under the commercial payer structure, the pharmacy is the entity contracted to supply the drugs, equipment, and supplies, and because of the dependency between these two components of care, commercial payers and accreditation organizations never separate the case management from the supplier of the drug, equipment, and supplies. Commenters recommended that the Secretary add a new requirement that the home infusion therapy supplier be enrolled in the DME program as a pharmacy that provides external infusion pumps and supplies, and that maintains all pharmacy licensure and accreditation requirements, and that all components of the home infusion benefit should be billed by the same provider, including professional services, drugs, pumps, and supplies.

Response: We recognize that there may be various providers and suppliers involved in a patient's care in the provision of home infusion therapy and the importance of care coordination. While the supplier furnishing the DME, home infusion drug, and related services may be the supplier furnishing the home infusion services, the statute does not require that the DME supplier also furnish home infusion therapy 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. There is no provision requiring the home infusion therapy supplier to furnish the infusion pump, drug, or other supplies. Further, section 1861(iii)(3)(D)(ii) of the Act allows a qualified home infusion therapy supplier to sub-contract with a pharmacy, physician, provider of services, or supplier to provide these services. Additionally, section 1861(u) of the Act defines ''provider of services'' to mean a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of sections 1814(g) and 1835(e) of the Act, a fund. Therefore, any of the previously noted entities who meet the Medicare accreditation requirements for home infusion therapy suppliers is eligible to enroll as a qualified home infusion therapy supplier.

We also do not anticipate a lapse in care coordination in the case that the home infusion therapy supplier is not the same entity furnishing the DME, drug, and related services. Section 1861(iii)(1)(B) of the Act states that the home infusion therapy plan of care must be established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs. As previously stated, this means that the home infusion plan of care must be established and reviewed by a physician in consultation with the DME supplier responsible for furnishing the home infusion drug and related services. Likewise, as discussed in the CY 2020 HH PPS proposed rule, the DME Quality Standards require the supplier (furnishing the infusion drug) to consult with the physician prescribing the infusion drug as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluation to the prescribed equipment item(s), and/or service(s) (84 FR 34692). Therefore, as the DME supplier is required to consult with the physician prescribing the infusion drug, initially and upon any changes in medication or orders, and the physician responsible for drafting the home infusion plan of care is required to consult with the DME supplier and the home infusion therapy supplier, we would expect the home infusion therapy plan of care to be current. Furthermore, proposed § 414.1515 requires that the home infusion plan of care contain the items indicated in § 486.520(b), which includes the specific medication, the prescribed dosage and frequency, as well as the professional services to be utilized for treatment, including the care and services necessary to meet patient-specific needs. Additionally, proposed § 414.1515 requires the plan of care to include the healthcare professional that will furnish each of the ordered services. Therefore, while the home infusion therapy supplier may not be the DME supplier, the home infusion plan of care must contain the required contents, as previously discussed, and established *in coordination* with the furnishing of the infusion drug. For this reason, in order to ensure that therapy is safe and effective throughout the course of treatment, as required by section 1861(iii)(1)(B) of the Act, the physician who orders the home infusion therapy services must review the plan of care on a regular basis, in coordination with the DME supplier, who is also required to consult with the physician prescribing the infusion drug.

Comment: A commenter requested that CMS clarify whether there will be a grace period for accreditation, and whether or not more accrediting bodies be added.

Response: Home Infusion Therapy (HIT) Accreditation Organizations will be held to the same expectations as our remaining accreditation organizations. The home infusion therapy application procedures and ongoing responsibilities are provided at 42 CFR part 488, subpart L. Any accreditation organization will be allowed to apply to be a CMS Approved Deeming Accreditation Organization for Home Infusion

Therapy, if the organization meets all of the requirements provided at 42 CFR 488.1010. Applications will be considered for the January 1, 2021 designation deadline, if the application is received by April 1, 2020.

Comment: Several commenters indicated that reimbursement under the DME benefit is inadequate to cover the home infusion therapy professional services and stated that Congress understood that the breadth and frequency of these services exceeds the scope of the DME benefit. Other commenters stated that the home infusion therapy payment was intended to make up for the drug pricing change from AWP to ASP plus 6 percent. Commenters stated that it is for these reasons that Congress created the home infusion therapy benefit and intended for these services, most notably those provided remotely by a pharmacist, to be reimbursed without regard to overlap with the DME benefit or contingent on the patient's nursing needs. Additionally, commenters stated that it is notable that Congress exempted training and education that is not otherwise paid for as DME from the professional services reimbursement, but made no such exemption for professional services, remote monitoring and monitoring services, or the other professional services referenced in the proposed rule.

Response: We are unsure of whether Congressional intent for the home infusion benefit was to reimburse providers for the change in drug pricing. However, in general, Medicare does not implement new benefits in order to subsidize other existing benefits. Additionally, because the home infusion therapy services payment does not include payment for the DME or the home infusion drug, the adequacy of the drug pricing is out of the scope for this final rule with comment period. Although the commenter stated that the home infusion therapy payment is for services ''without regard to overlap with DME,'' it is important to note that Medicare does not make duplicative payment for services, therefore we would not require two benefits to furnish the same services.

Additionally, CMS did not define or enumerate the professional services under the home infusion therapy benefit in order to avoid inadvertently excluding certain services. However, we agree that it is notable that training and education not otherwise paid for as DME is exempted from the professional services covered under the home infusion therapy benefit. The training and education provided under the DME benefit are services that would likely be furnished in the patient's home. Therefore, in order to avoid making duplicative payment, the training and education furnished under the DME benefit is explicitly excluded from the home infusion therapy services payment. Furthermore, as we noted in the CY 2019 HH PPS proposed rule, we consider the home infusion benefit principally to be a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the home infusion therapy services (83 FR 32466). Therefore, the professional services covered under the DME benefit are not covered under the home infusion benefit. While the two benefits exist in tandem, the services are unique to each benefit and billed and paid for under separate payment systems.

5. Home Infusion Therapy and the Interaction With Home Health

In the proposed rule, we discussed the potential for overlap between the new home infusion therapy benefit and the home health benefit. 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.

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, we stated 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 is excluded from the consolidated billing requirements governing the HH PPS (42 CFR 484.205) and therefore, the DME items and services (including the home infusion 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 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.

Comment: Several commenters expressed concern that home health agencies will not be able to bill for the home infusion therapy services for beneficiaries under a home health plan of care, unless they are also accredited as a home infusion therapy supplier. Commenters expressed concern that this is in contrast to the full coverage currently available for beneficiaries under the home health benefit, and that beneficiaries will now be responsible for a 20 percent coinsurance. Additionally, commenters stated that the home health agency would be responsible for providing the pump, medication, and infusion supplies if they did obtain the designation, and expressed concern that many HHAs believe that this is outside of their scope of practice. Commenters stated that HHAs will restrict the availability of infusion services and limit those patients needing infusion services, forcing many of these patients to receive their infusions at another setting rather than receiving them at home. A commenter recommended that the home infusion benefit should only be available for beneficiaries who are not homebound, and infusion services for otherwise eligible home health beneficiaries should remain under the home health benefit.

Response: We understand commenter concern regarding home infusion therapy services under the home health benefit; however, 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 January 1, 2021. Therefore, home infusion therapy will no longer be provided to homebound patients under the home health benefit. Home infusion therapy services will now be provided under the home infusion benefit for both homebound and non-homebound beneficiaries. It is also important to note, that the HHA is not responsible for furnishing the pump, related supplies, or the infusion medication. Further, the HHA is already required to arrange for the DME and related infusion services for patients under a home health plan of care. In the case that an HHA also becomes accredited as a home infusion therapy supplier, the HHA would continue to meet the requirements under the Home Health Conditions of Participation (CoPs) as well as the home infusion therapy supplier requirements as set out in Part 486, Subpart I, of which DME services, including pharmacy services associated with the preparation and dispensing of home infusion drugs are not included. We acknowledged in the CY 2019 HH PPS final rule with comment period that while these services are closely related to the home infusion therapy benefit, they remain covered under the Part B DME benefit and are not part of the Medicare home infusion therapy benefit (83 FR 56563).

6. 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 treatment 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 record before establishing the infusion 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. The frequency of discussing these options could vary based on a routine scheduled visit or according to the individual's clinical needs.

We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716), as well as the CY 2020 HH PPS proposed rule (84 FR 34694), regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to his/her patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also solicited comments on any additional interpretations of this notification requirement and whether this requirement is already being met under the temporary transitional payment for home infusion therapy services.

The following is a summary of the related comments received on both solicitations.

Comment: Several commenters supported the proposed examples of the physician verbally discussing the infusion therapy options and annotating the resulting decision in the medical record and initial plan of care. Many commenters stated that written materials may be a helpful supplement to a verbal conversation, but written materials should not be the sole means of beneficiary notification. They emphasized that infusion therapy options should be verbally discussed so the patient, and any family caregiver, may have an opportunity to get immediate answers to questions that may not be addressed in written materials. Many commenters encouraged CMS to consider minimizing the paperwork burden and confusion that written documents or patient attestations could impose on physicians and patients.

Commenters recommended that the conversation should include how the infusion therapy options differ in terms of effectiveness, safety, time, comfort, convenience, location, frequency, and out-of-pocket costs. Some commenters specifically noted that beneficiaries are subject to the standard 20 percent coinsurance with this new Part B benefit; and the ordering physician should be aware of the patient's insurance status and therefore assist them in making informed decisions about their care.

Some commenters recommended the policy should allow for other professionals, such as social workers, home health nurses, and other staff to assist the treating physician with this notification in order to remove unnecessary administrative burden for clinicians. Commenters also requested that the notification policy include requirements would be simple and easy for physicians to implement, and that would retain the current flexibility for physicians to use multiple notification mechanisms as directly suggested by beneficiaries, advocates and stakeholders.

One commenter requested that CMS follow similar procedures for other electronically prompted beneficiary notifications. Another commenter recommended that CMS develop a single standardized format for this notice to avoid benefit denials and delays in therapy. Another commenter suggested that CMS establish a training program for physicians, hospitals and contractors prior to implementation.

A commenter requested that CMS permit sufficient time for physicians to research the available home infusion therapy options. Another commenter requested that CMS create a web page where a beneficiary or referring clinician can research if there is a home infusion therapy supplier in the beneficiary's geographic location that is capable of delivering these services, and that the supplier is enrolled and approved by Medicare.

A few commenters asked that this notification be required only when the drug regimen is available and appropriate for home infusion therapy. They suggested that notification should not be required if there are certain safety risks associated with infusion therapy in that patient's home or if the home infusion therapy option is not available in the patient's geographic area.

Regarding the frequency of notification, one commenter suggested that only one streamlined notice be required at the start of therapy because many therapies have a duration for the life of the beneficiary. Two commenters specified that notification of options should be discussed and documented in the patient record whenever a new infusion therapy treatment is deemed necessary by the physician and anytime thereafter if there are changes in patient condition or circumstances that would affect the patient's choices.

Response: We appreciate the commenters' support and recommendations and will take the comments into consideration as we continue developing future policy through notice-and-comment rulemaking effective for home infusion therapy services beginning CY 2021 and for subsequent years.

D. Payment Categories and Amounts for Home Infusion Therapy Services for CY 2021

In the CY 2020 HH PPS proposed rule we discussed section 1834(u)(1)(A)(i) of the Act, which requires the Secretary 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. Section 1834(u)(1)(B)(ii) of the Act requires the payment amount to reflect patient acuity and complexity of drug administration.

We stated 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. We proposed to maintain the three payment categories, with the associated J-codes, utilized currently under the temporary transitional payment. We stated that this utilizes an already established framework for assigning a unit of single payment (per category), accounting for different therapy types, which in turn, reflects variations in nursing utilization, complexity of drug administration, and patient acuity. We stated that 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 CY 2021. Table 30 provides the list of J-codes associated with the infusion drugs that fall within each of the payment categories. We also noted that there are a few drugs for which services are included under the transitional benefit that would not be defined as home infusion drugs under the permanent benefit beginning with CY 2021.

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TABLE 30: 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 (for example, liquid), 500 mg
J1562 JB*	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB*	Injection, immune globulin, (gammagard liquid), non-lyophilized, (for example., 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.

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We stated in the proposed rule that 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 ''single payment amounts'' for the temporary transitional payments for home infusion therapy services. We also reiterated that a ''single payment amount'' for an infusion drug administration calendar day 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 proposed to carry forward the payment methodology as outlined in section 1834(u)(7)(A) of the Act for the temporary transitional payments. We proposed 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. 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 proposed 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, rather than retaining the current rate under the temporary transitional payment, equal to 4 hours. We stated that 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. We

stated that setting the payment amount at the maximum amount allowed by statute would reflect the varying degrees of care among individual patients within each category and from visit to visit for the same patient. It would also ensure that payment for home infusion therapy services adequately covers the different patient care needs and level of complexity of services provided, while remaining a unit of single payment. While the single unit of payment for the temporary transitional payments was set at 4 hours by law, the law for the permanent benefit provides more latitude for home infusion therapy services payments beginning in CY 2021. We stated that furnishing care in the patient's home is fundamentally different from furnishing care in the physician's office due to healthcare professionals being unable to achieve the economies of scale in the home that can be achieved in an office setting. Therefore, the single unit of payment is a bundle that 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 payment rates for each of the three payment categories are higher than the home health per-visit nursing rate of $149.68, the rate for medical social services is $239.92. As we did not limit this benefit to only nursing visits, the home infusion therapy rates for subsequent visits are comparable to the home health per visit amounts. The home infusion therapy rates reflect the increased complexity of the professional services provided per category, and as required by law. We continue to believe that increasing the payment amount to 5 hours will better account for all of the home infusion therapy services covered under the benefit, including nursing; training and education; remote monitoring; and monitoring provided on an infusion drug administration calendar day.

We also stated that 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. 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. We explained that one component used to value the CPT code, the non-facility practice expense relative value unit (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, and that 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.

We also recognized 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 accordance with section 1834(u)(1)(C) of the Act, which 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, we proposed 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. We stated 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, and that 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. We stated that 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 recognized 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, we stated that 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.

And finally, we stated that 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.

The following is a summary of the comments received on the proposed CY 2021 home infusion therapy categories and payment amounts, and our responses:

Comment: A few commenters' stated that the proposed categories do not necessarily reflect the acuity or complexity of drug administration. These commenters did not suggest other methods for grouping drugs but recommended that CMS reimburse all home infusion professional services at the proposed rate for payment category 3 (1 hour at CPT 96413 and 4 hours at CPT 96415). MedPAC recommended that CMS use 2019 home infusion therapy claims data to evaluate the three categories and consider whether modifications to the three categories are appropriate in next year's proposed rule.

Response: While commenters' did not provide a rationale as to why they believe all infusion drug administration calendar days should be paid at the payment category 3 rate, it is important to reiterate that CMS is required to account for varying therapy types under the payment system. Section 1834(u) of the Act requires the Secretary to implement a payment system under which a single payment is made to a home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services), beginning January 1, 2021. 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. Paying a single payment amount at the category 3 rate for the professional services for all home infusion drugs

would not take into account types of infusion therapy, including the variation in utilization of nursing services, patient acuity, and complexity of drug administration.

We appreciate MedPAC's suggestion to evaluate the three categories and consider whether modifications are appropriate for next year's rule. We will continue to monitor home infusion utilization using the temporary transitional payment claims data, including visit length. If adjustments to any of the home infusion therapy provisions are warranted based on this data analysis, we will address such changes in future rulemaking.

Comment: A commenter stated that the CPT description for the category three CPT codes are more expansive than only chemotherapy drugs, and noted that it can be used for ''injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration.''

Response: We recognize that the CPT code associated with payment category 3 home infusion drugs also includes other highly complex drugs and biologicals; however, currently the only drugs on the LCD for External Infusion Pumps (L33794) that are appropriate for this category are the cancer chemotherapy drugs. In the event that additional drugs or biologicals are added to the DME LCD, then potentially more drugs and biologicals (other than cancer chemotherapy drugs) would be included in payment category 3.

Comment: The majority of commenters supported the 5 hour payment rate; however, these commenters continued to disagree with the definition of ''infusion drug administration calendar day.'' Several commenters also stated they would support retaining the three payment categories and the rates that were established in the Bipartisan Budget Act of 2018 if CMS were to pay on each day the patient receives an infusion drug, regardless of whether a professional is in the home. MedPAC disagreed with the increase from a 4 hour payment rate to a 5 hour payment rate without sufficient evidence that this increase is warranted, or that increasing the aggregate level of payment to the maximum level permitted by statute is an appropriate approach for addressing variation in costs across patients. MedPAC also suggested considering other approaches to address variation in costs such as developing a payment adjuster for patient acuity or complexity of drug administration.

Response: We thank the commenters for their support for setting the payment rate to 5 hours of infusion in a physician's office. We believe that 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. We understand MedPAC's concern regarding the lack of evidence that such an increase in the number of hours is warranted. However, because the home infusion therapy payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type, yet remain a single payment amount, we do believe that setting the payment rate to the maximum amount set in statute recognizes the variety and amount of services included in the payment. Also, because we are implementing a payment system for a new Medicare benefit, we do not have sufficient data in order to examine situations for which payment adjustment (for example, a case-mix adjustment system) may be appropriate. As previously discussed, we plan to continue to monitor visit length in order to determine if adjustments in the payment methodology are needed. However, as we do not collect cost report data for suppliers, it is unclear how we would be able to evaluate data regarding variations in cost across patients.

We remind commenters that we finalized the definition of ''infusion drug administration calendar day'' in the CY 2019 HH PPS final rule with comment period (83 FR 56583) and we did not propose changes to this definition in the CY 2020 HH PPS proposed rule. Our responses to additional comments received on the CY 2019 HH PPS final rule with comment period with regard to this definition are addressed in section VI.C.1. of this final rule with comment period. Therefore, payment for home infusion therapy services beginning in CY 2021 will be for those days on which a skilled professional is in the patient's home furnishing home infusion therapy services during a day of drug administration.

Comment: Commenters were overwhelmingly in support of the proposed payment adjustment for the first visit. Commenters appreciated the recognition that new patients require more time and education. A commenter agreed that it is reasonable to expect that the first home infusion therapy visit will have higher associated costs, but encouraged CMS to examine claims data as it becomes available in order to determine an appropriate payment rate for the first versus subsequent visits.

Response: We thank commenters for their support of this proposal, and as previously stated, do plan on monitoring visit lengths in order to determine if the data substantiates this adjustment.

Comment: A few commenters recommended collecting the data necessary to construct a permanent rate that reflects the complexity and duration of services necessary to deliver home infusion therapy, will incentivize the delivery of safe, effective, high-quality care, and will inform future policy discussions as new and emerging medications become available.

Response: We appreciate commenters' recommendations and will consider them for the future as well as continue to monitor home infusion therapy utilization through the collection and analysis of claims data as previously discussed.

Final Decision: We are finalizing our proposal to maintain the three payment categories currently being utilized under the temporary transitional payments for home infusion therapy services. We are finalizing that each category payment amount will be in accordance with the six CPT infusion codes under the PFS and equal to 5 hours of infusion services in a physician's office. And finally, we are finalizing our proposal to increase 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, in a budget neutral manner, resulting in a small decrease to the payment amounts for any subsequent visits. Payment will be made for each infusion drug administration calendar day in accordance with the definition finalized in the CY 2019 final rule with comment period (83 FR 56583). We will continue to evaluate the home infusion therapy benefit and if appropriate and within the scope of our statutory authority, make adjustments to the payment methodology to maximize utilization of the home infusion therapy benefit, while protecting the integrity of the Medicare program.

In response to stakeholder concerns regarding the limitations of the DME LCDs for external infusion pumps that preclude coverage to certain infused drugs, we seek comments on the criteria CMS could consider to allow coverage of additional drugs under the DME benefit. In order for a drug to be covered as a supply under the Medicare DME benefit, the drug itself must require administration through an external infusion pump. Under this benefit, the DME Supplier Standards require that

the supplier train the patient and/or caregiver to operate the equipment safely and effectively in the home. As such, the patient and/or caregiver must be able to use the equipment on his/her own. For this reason, the DME LCDs for External Infusion Pumps do not currently include drugs that the patient and/or caregiver would not be able to infuse in the home without a healthcare professional present. However, given the new permanent home infusion therapy benefit to be implemented beginning January 1, 2021, which includes payment for professional services, including nursing; we are soliciting comments on options to enhance future efforts to improve policies related to coverage of eligible drugs for home infusion therapy (for example, whether coverage could include instances where diseases or conditions prevent a patient from being able to self-infuse, such as due to a neurodegenerative disease). We believe that any changes to the DME and home infusion therapy benefits must first ensure that the DME and supplies covered fall within the scope of the DME benefit, and also balance concerns of promoting access to innovative treatments with patient safety and cost-efficient delivery and monitoring of drug infusions relative to the facility setting (for example, physician office or hospital outpatient department).

Table 31 shows the payment categories with the CPT codes and units for such codes for home infusion therapy services in CY 2021 and subsequent calendar years. Table 32 illustrates the 5-hour payment rates (using the proposed CY 2020 PFS amounts) reflecting the increased payment for the first visit and the decreased payment for all subsequent visits. The actual home infusion payment rates will be updated in next year's rule using the CY 2021 PFS amounts.

TABLE 31: 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

TABLE 32: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FOR FIRST AND SUBSEQUENT VISITS

CPT Code	Description	2020 Proposed PFS Amounts	5-hour Payment -First Visit	5-hour Payment-Subsequent Visits
96365	Ther/proph/diag IV inf 1 hr	$71.45	$255.25	$153.54
96366	Ther/proph/diag IV inf add hr	$22.02		
96369	Sub Q Ther inf up to 1 hr	$161.32	$357.44	$215.00
96370	Sub Q Ther inf add hr	$15.52		
96413	Chemo IV inf 1 hr	$141.47	$422.70	$254.26
96415	Chemo IV inf add hr	$30.68		

E. Required Payment Adjustments for CY 2021 Home Infusion Therapy Services

1. 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 stated that we determined that the geographic adjustment factor (GAF) is a more appropriate option to adjust home infusion therapy payments based on differences in geographic area 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).[228] The work GPCI reflects the relative costs of physician labor by region. The PE GPCI measures the

[228] *GAF* = (.50886 × Work GPCI) + (.44839 × PE GPCI) + (.04295 × MP GPCI).

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 final rule with comment period 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 such as the hospital wage index (HWI), the GPCI, and using just the practice expense component of the GPCI. However, we proposed use of the GAF to geographically wage adjust home infusion therapy for CY 2021 and subsequent years. We stated that the GAF is the best option for geographic wage adjustment, as 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. The GAF is further discussed in the CY 2017 PFS final rule (81 FR 80170). The final CY 2020 and CY 2021 GAF values for each payment locality, when available, will be posted along with the final rule with comment period at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

We proposed that the application of the geographic wage adjustment be budget neutral so there is no overall cost impact. However, this results 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 will 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 received a comment that supported the use of geographic adjustment for the home infusion therapy benefit in CY 2021; however, we did not receive any comments specifically regarding the use of the GAF, or any other wage adjustment, to geographically adjust the home infusion therapy payment amounts.

Comment: A commenter stated support for the use of geographic payment indexing to ensure that in higher cost markets, reimbursement is in line with expenses.

Response: We appreciate the commenter's support, and will note that geographic adjustment is a statutory requirement for the home infusion therapy benefit beginning in CY 2021.

Final Decision: We are finalizing our proposal to use the GAF to geographically adjust the home infusion therapy payment amounts in CY 2021 and subsequent calendar years.

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 stated that 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.[229] Prior authorization helps to ensure that a service, such as home infusion therapy, is being provided appropriately.

In the CY 2020 HH PPS proposed rule (84 FR 34701), we discussed comments received on the CY 2019 HH PPS proposed rule solicitation of comments regarding whether and how prior authorization could potentially be applied under the home infusion benefit. We noted that 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 therapy.

Ultimately, we agreed with commenters and stated that 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. We stated that we will monitor

[229] Preauthorization. *https://www.healthcare.gov/glossary/preauthorization/.*

the provision of home infusion therapy services and revisit the need for prior authorization if issues arise.

We received a few comments on the CY 2020 HH PPS proposed rule regarding the use of prior authorization for the home infusion therapy benefit in CY 2021:

Comment: A commenter stated that requiring prior authorization from the prescriber for home infusion therapy services will not improve the safety or efficacy of care, as site of care choices in this context are only initiated by the prescribing physician. The commenter stated that the home infusion therapy supplier cannot unilaterally switch the care setting, and stated that further mandating prior authorization only delays initiation of home infusion therapy for the patient and adds administrative burden and costs to the process. Another commenter stated that implementing prior authorization for home infusion therapy, or any other home health service would be a duplication of physician effort (who have already determined reasonable and necessary), may result in delay of care, and potentially lead to a prior denial for legitimate care.

Response: We thank the commenters for their comments. As stated previously, we agree that prior authorization is not necessary for home infusion therapy at this time, but will continue to 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 2020 HH PPS proposed rule (84 FR 34701) we discussed comments received on the CY 2019 HH PPS proposed rule, regarding situations that may incur an outlier payment and potential designs for an outlier payment calculation. We stated that we planned to monitor the need for such payment and if necessary address outlier situations in future rule making. We received a comment regarding outliers for home infusion therapy services.

Comment: MedPAC suggested that although it may be premature to develop a system of outliers, developing such a system would be preferable to increasing aggregate payments for the purpose of addressing cost variation.

Response: We thank MedPAC for this recommendation and will pay close attention to any situations that would potentially be appropriate for an outlier payment, and if necessary address these situations in future rulemaking.

G. Billing Procedures for CY 2021 Home Infusion Therapy Services

Finally, in the CY 2020 HH PPS proposed rule we discussed billing procedures for home infusion therapy services for CY 2021 and subsequent years. We stated that because 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, the qualified home infusion therapy supplier will 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 home infusion therapy professional services to the A/B MAC. We stated that 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. We also plan to add the home infusion G-codes to the PFS, incorporating the required annual and geographic wage adjustments. Home infusion therapy suppliers will 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. We will issue a Change Request (CR) providing more detailed instruction regarding billing and policy information for home infusion therapy services, prior to implementation of the CY 2021 home infusion benefit.

Comment: Several commenters had concerns about the home infusion therapy supplier enrollment process with the A/B MACs, as the majority of suppliers are only enrolled as DME suppliers and only bill the DME MACs. They stated that the 855B A/B enrollment form does not include a category for ''home infusion therapy supplier'' and urged CMS to offer enrollment guidance. Commenters also pointed out that the DME supplier is not required to be in the same state as the patient, which allows the supplier to distribute drugs and supplies across a broad geographical region, thereby allowing continued service for Medicare beneficiaries who spend parts of the year in different states. They encouraged CMS to ensure that home infusion therapy suppliers are able to enroll in such a way that they can identify their pharmacy as a practice location and base-operation from which they schedule and dispatch nursing related home infusion services; allow for jurisdictional enrollment and billing of HIT services without the requirement to have a physical location within the jurisdiction; and allow for DME suppliers, also accredited as qualified home infusion therapy suppliers, to complete a single A/B MAC application identifying all areas that they schedule and dispatch the nursing component of home infusion therapy.

Response: We thank commenters for their review of the billing procedures outlined in the proposed rule. We recognize that the enrollment process will be new for the DME suppliers enrolling concurrently as home infusion therapy suppliers; however, we encourage commenters not to conflate DME suppliers with home infusion therapy suppliers. The DME taxonomy code, which, as the commenter pointed out, allows for pharmacy-based, decentralized patient care that does not require a physical brick-and mortar location, will not be affected by the requirement for home infusion therapy suppliers enrollment through the A/B MACs. DME suppliers are not required to enroll with the A/B MACs but instead they will continue to enroll with the National Supplier Clearinghouse, and their billing processes for equipment and supplies, including infusion drugs, will not change. Only if they become accredited as a home infusion therapy supplier, would they complete an additional enrollment with the A/B MACs in order to submit home infusion therapy service claims. We do understand that some current DME suppliers enrolling as home infusion therapy suppliers may not have brick-and-mortar locations per the A/B MAC requirements; however, and plan to issue more complete guidance for these providers.

We also recognize there is currently not a ''home infusion therapy supplier'' type on the 855B enrollment form, and

are considering creating one for home infusion supplier enrollment. In the meantime, providers can enroll using the ''other'' option. We are currently examining and working on all other aspects of the enrollment process and appreciate and will take all commenter suggestions under consideration as we continue developing guidance for suppliers.

VII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule. This home health proposed rule has previously been subjected to notice and comment procedures. These corrections do not make substantive changes to this policy. Specifically, we amended the definition of ''applicable provider'' at § 486.505 to read ''nurse practitioner'' rather than ''nurse provider.'' Additionally, we amended § 414.1550(a)(1) and (2) to include ''or service''. The specific changes we are making in the regulations are simply technical corrections in the language and do not reflect any additional substantive changes. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the CY 2020 final rule with comment period is unnecessary and contrary to the public interest.

Additionally, we are finalizing the submission of a ''no-pay'' RAP within five calendar days after the start of each 30-day period of care for CY 2021. We are also finalizing to apply a payment reduction if the ''no-pay'' RAP is not submitted timely. These changes were not proposed in the proposed rule, however, we are adopting the change here under a ''good cause'' waiver of proposed rulemaking. The specific changes we are making are in accordance with the proposed NOA policy for CY 2021. However, we are delaying the submission of a NOA until CY 2022 to allow sufficient time to make system changes to accommodate the NOA process. We note that if the NOA policy would have been finalized for CY 2021, the payment reduction for an untimely filed NOA would also be applied. Therefore, finalizing a ''no-pay'' RAP policy, as opposed to a NOA policy, with an untimely submission payment reduction in CY 2021 does not reflect any additional substantive changes to what was proposed. Therefore, we find that undertaking further notice and comment procedures to incorporate this correction into the final rule with comment period is unnecessary and contrary to the public interest.

VIII. 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 final rule with comment period, we are finalizing our proposed updates to the HH QRP with the exception of the removal of Question 10 from all HHCAHPS survey as discussed in Section V.K. We believe that the burden associated with the HH QRP provisions 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 2018 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 33.

TABLE 33: U.S. BUREAU OF LABOR STATISTICS' MAY 2018 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	$36.30	$36.30	$72.60
Physical therapists (PT)	29-1123	$42.73	$42.73	$85.46
Speech-Language Pathologists (SLP)	29-1127	$38.80	$38.80	$77.60
Occupational Therapists (OT)	29-1122	$41.04	$41.04	$82.08

As discussed in section V.D. of this final rule with comment period, we are finalizing the removal of 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 finalized the removal of 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 final rule with comment period, we are finalizing the adoption of 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 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 final rule with comment period, we are finalizing the collection of standardized patient assessment data beginning with the CY 2022 HH QRP. We estimate the 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 10.95 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 11.25 minutes at Discharge as a result of the HH QRP proposals finalized in this 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 $74.58, inclusive of fringe benefits, using the hourly wage data in Table 33. Individual providers determine the staffing resources necessary.

Table 34 shows the total number of OASIS assessments submitted by HHAs in CY 2018 and estimated burden at each time point.

TABLE 34: CY 2018 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time Point	CY 2018 Assessments Completed	Estimated Burden ($)
Start of Care	6,573,010	$79,659,951.44
Resumption of Care	1,113,156	$12,245,328.24
Follow-up	2,067,257	0
Transfer of Care	2,021,383	$753,773.72
Death at Home	42,550	0
Discharge from Agency	5,652,757	$79,046,740.70
TOTAL	**17,470,113**	$171,705,794.10

* 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 34, 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 $15,081.76 per HHA annually, or $171,705,794.10 for all HHAs annually. This corresponds to an estimated increase in clinician burden associated with changes to the HH QRP of approximately 202.2 hours per HHA annually, or 2,302,303.5 hours for all HHAs annually. This estimated increase in burden will be accounted for in the information collection under OMB control number 0938–1279.

IX. 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 heath 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, and is not reflective of cost estimates for CY 2020.

Section 50401 of the BBA of 2018 amended section 1834(u) of the Act, by adding a new paragraph (7). The paragraph 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 final rule with comment period), 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 continues 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).

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.

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 final rule with comment period:

- HH PPS—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). This reflects the effects of the CY 2020 home health payment update percentage of 1.5 percent ($290 million increase), and a 0.2 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2020 ($40 million decrease). The home health wage index update for CY 2020 and the updated FDL ratio that will be used for outlier payments in CY 2020 are both budget-neutral.

- 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 policy finalized in this final rule with comment period would affect the prior estimate.

- HH QRP—The cost impact for HHA's related to proposed changes to the HH QRP are estimated at $167.8 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 an estimated 1.9 percent, or $1.2 million, decrease in payments to home infusion therapy suppliers in CY 2020 based on the proposed CY 2020 Physician Fee Schedule (PFS) payment amounts for such services (the final CY 2020 PFS payment amounts were not available in time for this final rule with comment period). The cost impact in CY 2021 related to the implementation of the permanent home infusion therapy benefit is estimated to be a $2 million reduction in payments to home infusion therapy suppliers.

C. Anticipated Effects

1. HH PPS and Home Infusion Therapy

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 in this final rule with comment period will result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs and home infusions therapy suppliers. Therefore, the Secretary has determined that this HH PPS final rule with comment period will have a significant economic impact on a substantial number of small entities. We refer stakeholders to Tables 35 and 36 which contain some information on the numbers of small entities impacted by the rule.

In addition, section 1102(b) of the Act requires us to prepare a final RIA if a rule has a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is not applicable to hospitals. Therefore, the Secretary has determined this final rule with comment period 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 final rule with comment period under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

One commenter expressed concerns that CMS is not considering the requirements of the Regulatory Flexibility Act or the Small Business Regulatory Enforcement Fairness Act, which limits the impact on small businesses. We refer commenters to section III.B. of this final rule with comment period for our response to this comment.

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 policy that we are finalizing will affect the prior estimate.

3. HH QRP

Section VIII. of this final rule with comment period provides a detailed description of the net increase in burden associated with changes to the HH QRP. 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 $171.7 million in annualized cost to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2021.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule with comment period, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique reviewers of this year's final rule with comment period would be the similar to the number of reviewers on last year's final rule with comment period. 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 with comment period 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 also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. While we solicited comments on the approach in estimating the number of entities which would review the proposed rule and the assumption of how much of the rule reviewers would read, we did not receive any comments. Therefore, 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 with comment period 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 5 hours for the staff to review half of this final rule with comment period, which consists of approximately 152,000 words. For each HHA that reviews the final rule with comment period, the estimated cost is $546.80 (5 hours × $109.36). Therefore, we estimate that the total cost of reviewing this final rule with comment period is $292,632 ($546.80 × 537 reviewers).

D. Detailed Economic Analysis

1. HH PPS

This final rule with comment period finalizes updates to Medicare payments under the HH PPS for the CY 2020. This rule with comment period also implements changes 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. The impact analysis of this final rule with comment period presents the estimated expenditure effects of policy changes finalized 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 35 represents how HHA revenues are likely to be affected by the policy changes in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2018 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2018 (as of July 31, 2019). The first column of Table 35 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 finalized in this rule with comment period.

Overall, it is projected that aggregate payments in CY 2020 would increase by 1.3 percent. As illustrated in Table 35, 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.

TABLE 35: 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	10,185	0%	-0.2%	0.0%	1.5%	1.3%
Facility Type and Control						
Free-Standing/Other Vol/NP	1,014	-0.2%	-0.1%	2.5%	1.5%	3.7%
Free-Standing/Other Proprietary	8,157	0.0%	-0.1%	-1.1%	1.5%	0.3%
Free-Standing/Other Government	233	-0.1%	-0.4%	2.5%	1.5%	3.5%
Facility-Based Vol/NP	549	-0.1%	-0.2%	3.6%	1.5%	4.8%
Facility-Based Proprietary	63	0.2%	-0.3%	2.9%	1.5%	4.3%
Facility-Based Government	169	0.4%	-0.4%	4.4%	1.5%	5.9%
Subtotal: Freestanding	9,404	-0.1%	-0.1%	-0.3%	1.5%	1.0%
Subtotal: Facility-based	781	0.0%	-0.2%	3.7%	1.5%	5.0%
Subtotal: Vol/NP	1,563	-0.2%	-0.1%	2.8%	1.5%	4.0%
Subtotal: Proprietary	8,220	0.0%	-0.1%	-1.1%	1.5%	0.3%
Subtotal: Government	402	0.2%	-0.4%	3.6%	1.5%	4.9%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	248	-0.3%	-0.7%	3.7%	1.5%	4.2%
Free-Standing/Other Proprietary	820	0.2%	-0.7%	3.4%	1.5%	4.4%
Free-Standing/Other Government	152	0.1%	-0.8%	0.3%	1.5%	1.1%
Facility-Based Vol/NP	245	0.6%	-0.8%	3.4%	1.5%	4.7%
Facility-Based Proprietary	33	0.3%	-0.8%	10.4%	1.5%	11.4%
Facility-Based Government	132	0.3%	-0.8%	4.6%	1.5%	5.6%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	766	-0.2%	0.0%	2.3%	1.5%	3.6%
Free-Standing/Other Proprietary	7,337	-0.1%	-0.1%	-1.7%	1.5%	-0.4%
Free-Standing/Other Government	81	-0.3%	0.0%	4.3%	1.5%	5.5%
Facility-Based Vol/NP	304	-0.2%	-0.1%	3.7%	1.5%	4.9%
Facility-Based Proprietary	30	0.1%	-0.1%	-0.4%	1.5%	1.1%
Facility-Based Government	37	0.5%	-0.1%	4.1%	1.5%	6.0%
Facility Location: Urban or Rural						
Rural	1,630	0.2%	-0.7%	3.5%	1.5%	4.5%
Urban	8,555	-0.1%	-0.1%	-0.5%	1.5%	0.8%

Facility Location: Region of the Country (Census Region)						
New England	355	-0.7%	-0.1%	2.5%	1.5%	3.2%
Mid Atlantic	469	-0.2%	-0.1%	3.0%	1.5%	4.2%
East North Central	1,896	-0.1%	-0.1%	-0.9%	1.5%	0.4%
West North Central	681	0.5%	-0.3%	-4.2%	1.5%	-2.5%
South Atlantic	1,612	-0.2%	-0.1%	-4.9%	1.5%	-3.7%
East South Central	410	0.1%	-0.4%	0.5%	1.5%	1.7%
West South Central	2,577	0.2%	-0.2%	4.1%	1.5%	5.6%
Mountain	692	0.1%	-0.1%	-5.4%	1.5%	-3.9%
Pacific	1,448	0.0%	0.0%	3.7%	1.5%	5.2%
Outlying	45	-0.4%	-0.3%	11.9%	1.5%	12.7%
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,741	0.2%	-0.1%	2.5%	1.5%	4.1%
100 to 249	2,154	0.1%	-0.1%	0.9%	1.5%	2.4%
250 to 499	2,134	0.1%	-0.1%	0.6%	1.5%	2.1%
500 to 999	1,660	0.0%	-0.2%	-0.3%	1.5%	1.0%
1,000 or More	1,496	-0.1%	-0.1%	-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 (as of July 31, 2019).

[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 final rule with comment period.

Notes: This analysis omits 307,949 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 28 periods were excluded with missing NRS weights, and 2,869 periods with a missing urban/rural indicator; in total 9,336,898 30-day periods were used in the analysis.

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
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

2. HHVBP

As discussed in section IV. of this final rule with comment period, for the HHVBP Model, we proposed and are finalizing the public reporting of certain performance data for PY 5 (CY 2020) of the Model. This finalized policy does not affect our analysis of the distribution of payment adjustments for PY 5 as presented in the CY 2019 HH PPS final rule with comment period. 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 final rule with comment period, we proposed to remove one measure beginning with the CY 2022 HH QRP. The measure we proposed to remove is Improvement in Pain Interfering with Activity Measure (NQF #0177). As discussed in section V.E. of this final rule with comment period, we proposed to add two measures beginning with the CY 2022 HH QRP. The two measures we proposed 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 final rule with comment period, we are also proposed to collect standardized patient assessment data beginning with the CY 2022 HH QRP. Section VII. of this final rule with comment period 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 $167.8 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

The impact due to the updated payment amounts for furnishing home infusion therapy services is determined based on the rates published in the physician fee schedule established under section 1848 of the Act. At the time of publication of this final rule with comment period, the CY 2020 PFS final payment rates were not available. However, we estimate the impact in CY 2020, based on the CY 2020 PFS proposed rates, would result in a 1.9 percent decrease in overall payments for home infusion therapy suppliers receiving temporary transitional payments.

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 2021. We used CY 2018 claims data to identify beneficiaries with DME claims containing 1 of the 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 insulin, 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 with comment period. 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 CY 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. Additionally for these categories, 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 category 2, we assumed 1 visit per month, or 12 visits per year. 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 will 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 during the temporary transitional payment period, and once the permanent benefit is implemented in CY 2021.

Table 36 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 2020 transitional payment to the estimated CY 2021 payment after applying the geographic adjustment factor (GAF). Column 4 represents the percent change from the estimated CY 2021 payment after applying the GAF to the estimated CY 2021 payment after removing the statutorily excluded drugs and biologicals. Column 5 represents the percent change from the estimated CY 2021 payment after applying the GAF and removing the statutorily excluded drugs and biologicals to the estimated CY 2021 payment, and after applying the higher reimbursement rate. Overall, we estimate a 3.6 percent decrease ($2 million) in payments to home infusion therapy suppliers in CY 2021.

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TABLE 36: ESTIMATED IMPACTS FOR HOME INFUSION THERAPY SERVICES, CY 2021

	Number of Beneficiaries	CY 2021 Geographic Adjustment Factor (GAF)	CY 2021 Statutorily Excluded Drugs	CY 2021 Payment Proposal	Total
All Beneficiaries	18,704	0.0%	-14.8%	11.2%	-3.6%
Beneficiary Location: Urban or Rural					
Urban	15,494	0.8%	-15.1%	11.2%	-3.1%
Rural	3,210	-4.0%	-13.2%	11.1%	-6.0%
Beneficiary Location: Region of the Country (Census Division)					
New England	769	4.2%	-20.7%	11.1%	-5.3%
Mid-Atlantic	3,448	4.5%	-6.3%	13.1%	11.3%
East North Central	2,460	-2.5%	-11.6%	11.7%	-2.4%
West North Central	1,361	-4.5%	-17.2%	10.1%	-11.6%
South Atlantic	4,802	-0.8%	-17.7%	10.5%	-8.0%
East South Central	1,246	-7.1%	-20.5%	9.2%	-18.4%
West South Central	1,863	-4.1%	-13.8%	10.8%	-7.1%
Mountain	991	-1.4%	-26.2%	9.0%	-18.6%
Pacific	1,747	6.5%	-18.1%	11.4%	-0.3%
Other	17	0.1%	-0.1%	13.2%	13.1%
Payment Category					
BBA Category 1	6,297	0.0%	-0.1%	16.0%	15.9%
BBA Category 2	7,402	-0.3%	-45.1%	4.1%	-41.3%
BBA Category 3	5,005	0.2%	-0.1%	13.2%	13.3%

Source: CY 2018 Medicare DME claims data as of August, 2019 containing HCPCS codes equal to one of the 37 codes listed in the BBA of 2018.

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
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

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E. Alternatives Considered

1. HH PPS

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

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, for the reasons discussed in section IV. of this final rule with comment period, we are finalizing the public reporting of the HHVBP Model performance data for PY 5 as proposed. 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 final rule with comment period, 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 proposed 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 provision.

The finalization of 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 addressed 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

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

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 37, 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 38 shows the burden to HHA's for submission of OASIS. Table 39 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers for home infusion therapy beginning in CY 2021.

TABLE 37: 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 38: 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 39: ACCOUNTING STATEMENT: PAYMENT FOR HOME INFUSION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2020 TO 2021

Category	Transfers
Annualized Monetized Transfers	-$2 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 final rule with comment period 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. This reflects the effects of the CY 2020 home health payment update percentage of 1.5 percent ($290 million increase), and a 0.2 percent decrease in payments due to the declining rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2020 ($40 million decrease). The home health wage index update for CY 2020 and the updated FDL ratio that will be used for outlier payments in CY 2020 are both budget-neutral. Effects of the implementation of the PDGM and the change to a 30-day unit of payment are also budget-neutral.

2. HHVBP

In conclusion, as noted previously for the HHVBP Model, we are finalizing our proposal to publicly report performance data for PY 5 (CY 2020) of the Model. This finalized policy does not affect our analysis of the distribution of payment adjustments for PY 5 as presented in the CY 2019 HH PPS final rule with comment period.

We estimate there would be no net impact (to include either a net increase or reduction in payments) for this final rule with comment period 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 changes to the HH QRP effective on January 1, 2021 result in a net additional annualized cost of $167.8 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 a 1.9 percent, or $1.2 million, decrease in payments to home infusion therapy suppliers in CY 2020 based on the proposed CY 2020 Physician Fee Schedule (PFS) payment amounts for such services established under section 1848 of the Act (the final CY 2020 PFS payment amounts were not available in time for this final rule with comment period).

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 $2 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 final rule with comment period 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.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 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 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 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)(1).

■ 5. Add subpart P to read as follows:

Subpart P—Home Infusion Therapy Services Payment

Conditions for Payment

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 the following requirements:

(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 or service.

(2) The fee schedule amount for the item or service, 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.* (i) 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 medicare equipment local coverage determination (DME LCD) for external infusion pumps.

(ii) Payment equals 1 unit of 96365 plus 4 units of 96366.

(2) *Category 2.* (i) Includes certain subcutaneous infusion drugs for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions.

(ii) 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 (d)(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 the 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 1395(hh) 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);

■ b. Adding paragraphs (g)(3) and (4);

■ c. Revising the heading for paragraph (h); and

■ d. Adding paragraphs (i) and (j).

The revisions and additions read as follows:

§ 484.205 Basis of payment.

* * * * *

(g) * * *

(2) *Split percentage payments for periods beginning on or after January 1, 2020 through December 31, 2020*—(i) *HHAs certified for participation 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.* Split percentage payments are not made to HHAs that are certified for participation in Medicare effective on or after January 1, 2019. Newly enrolled HHAs must submit a request for anticipated payment, which is set at 0 percent, at the beginning of every 30-day period. 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) *Split percentage payments for periods beginning on or after January 1, 2021 through December 31, 2021.* All HHAs must submit a request for anticipated payment within 5 calendar days after the start of care date for initial 30-day periods and within 5 calendar days after the ''from date'' for each subsequent 30-day period of care, which is set at 0 percent at the beginning of every 30-day period. HHAs receive a single payment for a 30-day period of care after the final claim is submitted.

(4) *Payments for periods beginning on or after January 1, 2022.* All HHAs must submit a Notice of Admission (NOA) at the beginning of the initial 30-day period of care as described in paragraph (j) of this section. HHAs receive a single payment for a 30-day period of care after the final claim is submitted.

(h) *Requests for anticipated payment (RAP) for 30-day periods of care starting on January 1, 2020 through December 31, 2020.* * * *

(i) *Submission of RAPs for CY 2021*—(1) *General.* All HHAs must submit a RAP, which is to be paid at 0 percent, within 5 calendar days after the start of care and within 5 calendar days after the ''from date'' for each subsequent 30-day period of care.

(2) *Criteria for RAP submission for CY 2021.* The HHA shall submit RAPs only when all of the following conditions are met:

(i) Once physician's written or verbal orders that contain the services required for the initial visit have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(ii) The initial visit within the 60-day certification period must have been made and the individual admitted to home health care.

(3) *Consequences of failure to submit a timely RAP.* When a home health agency does not file the required RAP for its Medicare patients within 5 calendar days after the start of each 30-day period of care—

(i) Medicare does not pay for those days of home health services based on the ''from date'' on the claim to the date of filing of the RAP;

(ii) The wage and case-mix adjusted 30-day period payment amount is reduced by 1/30th for each day from the home health based on the ''from date'' on the claim until the date of filing of the RAP;

(iii) No LUPA payments are made that fall within the late period;

(iv) The payment reduction cannot exceed the total payment of the claim; and

(v)(A) The non-covered days are a provider liability; and

(B) The provider must not bill the beneficiary for the non-covered days.

(4) *Exception to the consequences for filing the RAP late.* (i) CMS may waive the consequences of failure to submit a timely-filed RAP specified in paragraph (i)(3) 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)(3) 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.

(j) *Submission of Notice of Admission (NOA)*—(1) *For periods of care that begin on and after January 1, 2022.* For all 30-day periods of care after January 1, 2022, all HHAs must submit a Notice of Admission (NOA) to their Medicare contractor within 5 calendar days after the start of care date. The NOA is a one-time submission to establish the home health period of care and covers contiguous 30-day periods of care until the individual is discharged from Medicare home health services.

(2) *Criteria for NOA submission.* In order to submit the NOA, the following criteria must be met:

(i) Once a physician's written or verbal orders that contains the services required for the initial visit have been received and documented as required at §§ 484.60(b) and 409.43(d) of this chapter.

(ii) The initial visit must have been made and the individual admitted to home health care.

(3) *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 and case-mix 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 of filing of 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; and

(v)(A) The non-covered days are a provider liability; and

(B) The provider must not bill the beneficiary for the non-covered days.

(4) *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 (j)(3) 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 (j)(3) 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); and
■ 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, an 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 to CMS 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 the requirements in this paragraph (b)(1)(iii)(C) are approved by CMS.

(D) *Disapproval by CMS.* No organization, firm, or business that owns, operates, or provides staffing for an 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 are 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 paragraph (b) of this section must be submitted in the form and manner, and at a time, specified by CMS.

(c) *Exceptions and extension requirements.* (1) An 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) An HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS HHAPU reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) HHA CMS Certification Number (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) 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 an 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 the CMS-designated data submission 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 as stated in the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS does not consider a reconsideration request unless the HHA has complied fully with the submission requirements in paragraphs (d)(1) and (2) of this section.

(4) CMS makes a decision on the request for reconsideration and provide notice of the decision to the HHA 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.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 13. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 14. Section 486.505 is amended by revising the definition of ''Applicable provider'' to read as follows:

§ 486.505 Definitions.

* * * * *

Applicable provider means a physician, a nurse practitioner, and a physician assistant.

* * * * *

Dated: October 24, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 28, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–24026 Filed 10–31–19; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413 et al.
Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413 and 414

[CMS–1713–F]

RIN 0938–AT70

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2020. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This rule also updates requirements for the ESRD Quality Incentive Program (QIP). In addition, this rule establishes a methodology for calculating fee schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services, and a methodology for making adjustments to the fee schedule amounts established using supplier or commercial prices if such prices decrease within 5 years of establishing the initial fee schedule amounts. This rule also revises existing regulations related to the DMEPOS competitive bidding program. This rule also streamlines the requirements for ordering DMEPOS items, and develops a new list of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements. Finally, this rule summarizes responses to requests for information on data collection resulting from the ESRD PPS technical expert panel, changing the basis for the ESRD PPS wage index, and new requirements for the competitive bidding of diabetic testing strips.

DATES: These regulations are effective January 1, 2020.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS, and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

DMEPOS@cms.hhs.gov, for issues related to DMEPOS payment policy.

Julia Howard, (410) 786–8645, for issues related to DMEPOS CBP Amendments.

Jennifer Phillips, (410) 786–1023; Olufemi Shodeke, (410) 786–1649; and Maria Ciccanti, (410) 786–3107, for issues related to the DMEPOS written order, face-to-face encounter, and prior authorization requirements.

SUPPLEMENTARY INFORMATION:

Addenda Are Only Available Through the Internet on the CMS Website

The Addenda for the annual ESRD PPS proposed and final rules will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp.* In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html.* Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov.*

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

I. Executive Summary

A. Purpose

This final rule finalizes changes related to the End-Stage Renal Disease

(ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, the DMEPOS Competitive Bidding Program (CBP), and the regulations governing DMEPOS orders, face-to-face encounters, and prior authorization.

In future rulemaking years, the DMEPOS provisions will be in a separate rule from the ESRD PPS, AKI and ESRD QIP provisions.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates and makes revisions to the ESRD PPS for CY 2020.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI payment rate for CY 2020.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This final rule finalizes several updates to the ESRD QIP.

4. DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule establishes a gap-filling methodology for the pricing of new DMEPOS items and services in accordance with sections 1834(a), (h), (i) and 1833(o) of the Act for DME, prosthetic devices, orthotics, prosthetics, surgical dressings, and custom molded shoes, extra-depth shoes, and inserts, and section 1842(b) for parental and enteral nutrients (PEN) and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

This rule finalizes a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule will streamline the requirements for ordering DMEPOS items. It will also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2020:* The final CY 2020 ESRD PPS base rate is $239.33. This amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.7 percent), and application of the wage index budget-neutrality adjustment factor (1.000244), equaling $239.33 ($235.27 × 1.017 × 1.000244 = $239.33).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2020, we are updating the wage index values to the latest available data.
- *Update to the outlier policy:* We are updating the outlier policy using the most current data, as well as updating the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2020 using CY 2018 claims data. Based on the use of the latest available data, the final FDL amount for pediatric beneficiaries will decrease from $57.14 to $41.04, and the MAP amount will decrease from $35.18 to $32.32, as compared to CY 2019 values. For adult beneficiaries, the final FDL amount will decrease from $65.11 to $48.33, and the MAP amount will decrease from $38.51 to $35.78. The 1.0 percent target for outlier payments was not achieved in CY 2018. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent. We believe using CY 2018 claims data to update the outlier MAP and FDL amounts for CY 2020 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.
- *Eligibility criteria for the transitional drug add-on payment adjustment (TDAPA):* We are finalizing revisions to the drug designation process regulation at 42 CFR 413.234 for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Specifically, we are excluding drugs approved by the Food and Drug Administration (FDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8—from being eligible for the transitional drug add-on payment adjustment (TDAPA), effective January 1, 2020.
- *Modification of the basis of payment for the TDAPA for calcimimetics:* We will continue to pay the TDAPA for calcimimetics for a third year in CY 2020 in order to collect

sufficient claims data for rate setting analysis, but we are finalizing a reduction to the basis of payment for the TDAPA for calcimimetics for CY 2020 from the average sales price plus 6 percent (ASP+6) methodology to 100 percent of ASP.

- *Average sales price (ASP) conditional policy for application of the TDAPA:* Effective January 1, 2020, the basis of payment for the TDAPA for all new renal dialysis drugs and biological products is ASP+0, but if ASP data is not available, then we use Wholesale Acquisition Cost (WAC) +0, and if WAC is not available, then we use invoice pricing. We are finalizing a policy to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for that product. We will no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. We are also finalizing a policy to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive the latest full calendar quarter of ASP data for the product, beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.
- *New and innovative renal dialysis equipment and supplies:* We are finalizing our proposal to establish a transitional add-on payment adjustment to support ESRD facilities in the uptake of certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. We will pay this adjustment, which we are calling the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), for equipment and supplies that: (1) Have been designated by CMS as a renal dialysis service, (2) are new, meaning granted marketing authorization by FDA on or after January 1, 2020, (3) are commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) have a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) are innovative, meaning they meet the substantial clinical improvement (SCI) criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at 42 CFR 412.87(b)(1) and related guidance, and (6) are not capital-related assets. Specifically, the equipment or supply must represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year.

We are finalizing that the TPNIES will be based on 65 percent of the price established by the Medicare Administrative Contractors (MACs), using the information from the invoice and other relevant sources of information. We will pay the TPNIES for 2-calendar years, after which the equipment or supply will qualify as an outlier service and no change to the ESRD PPS base rate will be made.

- *Erythropoiesis-stimulating agent (ESA) monitoring policy (EMP*): We are discontinuing the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2020. The final CY 2020 payment rate is $239.33, which is the same as the base rate finalized under the ESRD PPS for CY 2020.

3. ESRD QIP

We are finalizing several new requirements for the ESRD QIP beginning with payment year (PY) 2022, including an updated scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure to allow new facilities and facilities that are eligible to report data on the measure for less than 12 months to be able to receive a score on that measure, and the conversion of the STrR clinical measure (National Quality Forum [NQF] #2979) to a reporting measure while we continue to examine concerns raised by stakeholders regarding the measure's validity. We are not finalizing our proposal to revise the scoring methodology for the MedRec reporting measure and will continue to score that measure using the methodology we adopted in the CY 2019 ESRD PPS final rule.

We are also finalizing the performance and baseline periods for the PY 2023 ESRD QIP and that, beginning with the PY 2024 payment year, we will automatically adopt performance and baseline periods that are advanced 1 year from those specified for the previous payment year.

Finally, we are updating our regulation text so that it better informs the public of the Program's requirements.

4. DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule finalizes a specific methodology for calculating fee schedule amounts for new DMEPOS items. The fiscal impact of establishing payment amounts for new items based on our proposal cannot be estimated as these new items are not identified and would vary in uniqueness and costs. However, there is some inherent risk that the methodology could result in fee schedule amounts for new items that greatly exceed the costs of furnishing the items.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

In cases where fee schedule amounts for new DMEPOS items and services are gap-filled using supplier or commercial prices, these prices may decrease over time. In cases where such prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts, this rule finalizes a one-time adjustment to the gap-filled fee schedule amounts. We will not make these price adjustments in cases where prices increase.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule will streamline the requirements for ordering DMEPOS items. It will also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

C. Summary of Costs and Benefits

In section X of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section X of this final rule displays the estimated change in payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the CY 2020 changes is projected to be a 1.6

percent increase in payments. Hospital-based ESRD facilities have an estimated 2.1 percent increase in payments compared with freestanding facilities with an estimated 1.6 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $210 million in CY 2020 compared to CY 2019. This reflects a $220 million increase from the payment rate update, a $50 million increase due to the updates to the outlier threshold amounts, and a $60 million decrease due to the change in the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent. These figures do not reflect estimated increases or decreases in expenditures based on the refinement to the TDAPA eligibility criteria, conditioning the TDAPA on the availability of ASP data, or providing the TPNIES. The fiscal impact of these policies cannot be determined because the new renal dialysis drugs and biological products eligible for the TDAPA and new renal dialysis equipment and supplies eligible for the TPNIES are not yet identified and would vary in uniqueness and costs. As a result of the projected 1.6 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2020, which translates to approximately $40 million.

2. Impacts of the Final Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section X of this final rule displays the estimated change in payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the CY 2020 changes is projected to be a 1.7 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.6 percent increase in payments compared with freestanding facilities with an estimated 1.7 percent increase.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the final CY 2020 ESRD PPS base rate will increase by less than $1 million in CY 2020 compared to CY 2019.

3. Impacts of the Final ESRD QIP Requirements

We estimate that the overall economic impact of the PY 2022 ESRD QIP will be approximately $229 million as a result of the policies we have previously finalized and the proposals we are finalizing in this final rule. The $229 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate will be approximately $211 million. We also estimate that the overall economic impact of the PY 2023 ESRD QIP will be approximately $223 million as a result of the policies we have previously finalized and are finalizing beginning with PY 2022. The $229 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate will be approximately $211 million.

4. Impacts of the Final DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This final rule establishes a specific methodology for calculating fee schedule amounts for new DMEPOS items. The fiscal impact of establishing payment amounts for new items based on this methodology cannot be estimated as the new DMEPOS items are not identified and would vary in uniqueness and costs. However, there is some inherent risk that the final methodology could result in fee schedule amounts for new items that greatly exceed the costs of furnishing the items.

b. Adjusting Gap-Filled Payment Amounts for DMEPOS Items and Services Using Supplier or Commercial Prices

We are finalizing a one-time adjustment to the gap-filled fee schedule amounts in cases where fee schedule amounts for new DMEPOS items and services are gap-filled using supplier or commercial prices, and these prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts. The one-time adjustment should generate savings although it will probably be a small offset to the potential increase in costs of establishing fee schedule amounts based on supplier invoices or prices from commercial payers. The fiscal impact for this provision is therefore considered negligible.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule streamlines the requirements for ordering DMEPOS items, and identifies the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

II. Calendar Year (CY) 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section

217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous (IV) product that is not considered included in the ESRD PPS bundled payment, meaning a product that is used to treat or manage a condition for which there is not an existing ESRD PPS functional category (§ 413.234). In the CY 2019 ESRD PPS final rule (83 FR 56929 through 56949), we finalized a policy to make the TDAPA available for all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories, effective January 1, 2020.

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 14, 2018, we published a final rule in the **Federal Register** titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS'' (83 FR 56922 through 57073) (hereinafter referred to as the CY 2019 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2019, the wage index, and the outlier policy, and we finalized revisions to the drug designation process and the low-volume payment adjustment. For further detailed information regarding these updates, see 83 FR 56922.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2020 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 38330 through 38421), hereinafter referred to as the ''CY 2020 ESRD PPS proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that proposed rule, for the ESRD PPS, we proposed to make a number of annual updates for CY 2020, including updates to the ESRD PPS base rate, wage index, and outlier policy. We also proposed revisions to the drug designation process regulation at 42 CFR 413.234 for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, a change in the basis of payment for the TDAPA for calcimimetics, and an average sales price (ASP) conditional policy for the application of the TDAPA. In addition, we proposed to establish a transitional add-on payment adjustment for certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. We also proposed to discontinue the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS.

We received approximately 92 public comments on our proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a

summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2020 ESRD PPS.

1. Eligibility Criteria for the Transitional Drug Add-On Payment Adjustment (TDAPA)

a. Background

Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and IV products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

In the CY 2016 ESRD PPS final rule, we also established in § 413.234(b)(2) that, if the new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA described in § 413.234(c). Then, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

After the publication of the CY 2016 ESRD PPS final rule, we continued to hear from the dialysis industry and other stakeholders with suggestions for improving the drug designation process. Therefore, in CY 2019 ESRD PPS rulemaking, we revisited the drug designation process to consider their concerns and we proposed policies that would mitigate these issues.

In the CY 2019 ESRD PPS final rule (83 FR 56929 through 56949), we finalized several provisions related to the drug designation process and the TDAPA under § 413.234, with an effective date of January 1, 2020. In particular, we finalized changes to the drug designation process regulation to: (1) Reflect that the process applies for all new renal dialysis drugs and biological products; (2) establish a definition for ''new renal dialysis drug or biological product''; (3) expand the eligibility criteria for the TDAPA; (4) change the TDAPA's basis of payment; and (5) extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. We discuss these changes in detail in the next several paragraphs.

First, we revised the drug designation process regulation at § 413.234 to reflect that the drug designation process applies for all new renal dialysis drugs and biological products that are approved by FDA, regardless of the form or route of administration, that are used to treat or manage a condition associated with ESRD. In the CY 2019 ESRD PPS proposed rule (83 FR 34309 through 34312), we described the prior rulemakings in which we addressed how new drugs and biological products are implemented under the ESRD PPS and how we have accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011. We explained that the drug designation process is dependent upon the ESRD PPS functional categories we developed, and is consistent with the policy we have followed since the inception of the ESRD PPS.

However, we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34311 through 34312) that, because section 217(c)(2) of PAMA only required the Secretary to establish a process for including new injectable and IV drugs and biological products in the ESRD PPS bundled payment, such new products were the primary focus of the regulation we adopted at § 413.234. We explained that we did not codify our full policy in the CY 2016 ESRD PPS final rule for other renal dialysis drugs, such as drugs and biological products with other forms of administration, including oral, which by law are included under the ESRD PPS (though oral-only renal dialysis drugs are excluded from the ESRD PPS bundled payment until CY 2025). Commenters were generally supportive of the proposal, and we finalized the changes to codify our drug designation policy with regard to all drugs.

Second, as part of our updates to the drug designation process regulation in the CY 2019 ESRD PPS final rule (83 FR 56929 through 56932), we replaced the definition of ''new injectable or intravenous product'' with a definition for ''new renal dialysis drug or biological product.'' Under the final definition, effective January 1, 2020, a ''new renal dialysis drug or biological product'' is an ''injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the [FDA] on or after January 1, 2020, under section 505 of the [FD&C Act] or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.''

Third, we expanded the eligibility criteria for the TDAPA to include all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories, in the CY 2019 ESRD PPS final rule (83 FR 56942 through 56843). In the CY 2019 ESRD PPS proposed rule (83 FR 34312 through 34314), we discussed a number of reasons why we were reconsidering our previous policy to limit the TDAPA to products for which there is not an ESRD PPS functional category. We

described the concerns that commenters had raised during the CY 2016 ESRD PPS rulemaking regarding the eligibility criteria for the TDAPA, including concerns about inadequate payment for renal dialysis services and hindrance of high-value innovation, and noted that these are important issues that we contemplate while determining appropriate payment policies. We discussed that when new drugs and biological products are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies into their care plans. We recognized that newly launched drugs and biological products can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes.

We explained in the CY 2019 ESRD PPS proposed rule that this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We stated that the TDAPA could provide flexibility and target payment for the use of new renal dialysis drugs and biological products during the period when a product is new to the market so that we can evaluate if resource use can be aligned with payment. We further explained that we believe we need to be conscious of ESRD facility resource use and the financial barriers that may be preventing uptake of innovative new drugs and biological products. Thus, we proposed to revise § 413.234(c) to reflect that the TDAPA would apply for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category, and, for those products that fall within an existing functional category, the payment would apply for only 2 years and there would be no subsequent modification to the ESRD PPS base rate (83 FR 34314). At the end of the 2 years, the product would be eligible for outlier payment unless it is a renal dialysis composite rate drug or biological product.

As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56934 through 56943), we received a variety of feedback from stakeholders on this proposal. Some commenters recommended delaying the expansion of the TDAPA and some urged CMS to consider different policy proposals. Some commenters were supportive of revising the drug designation process regulation to allow more drugs to be eligible for the TDAPA, while others expressed that the process needs to be further evaluated before any expansion. The Medicare Payment Advisory Commission (MedPAC) recommended that we not finalize the policy because it did not require that a new drug be more effective than current treatment and could undermine competition with existing drugs; or, if we do move forward with the policy, that we narrow eligibility to new drugs that fall into an existing ESRD PPS functional category only if they substantially improve beneficiaries' outcomes.

Other commenters had similar concerns and recommended that we require that the TDAPA apply for new renal dialysis drugs and biological products that have clinical superiority over the existing products in the existing functional categories, and they provided suggestions on clinical value criteria. In addition, some commenters believed that the TDAPA should not apply to generic drugs and biosimilar biological products. Commenters asserted that generic drugs and biosimilar biological products seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Commenters further believed that these types of drugs and biological products have no clinically meaningful differences and that they should be treated equally in payment and coverage policies. We also received several comments on our proposal to apply the TDAPA for a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate for 2 years, and to not modify the ESRD PPS base rate following payment of the TDAPA (83 FR 56934 through 56943).

After considering the public comments, in the CY 2019 ESRD PPS final rule, we finalized the expansion of the eligibility criteria for the TDAPA to reflect the proposed policy (83 FR 56943). We explained that there are 2 purposes of providing the TDAPA. For renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the purpose of the TDAPA is to help ESRD facilities to incorporate new drug and biological products and make appropriate changes in their businesses to adopt such products; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories. For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category and that are not considered to be reflected in the ESRD PPS base rate, the purpose of the TDAPA is to be a pathway toward a potential base rate modification (83 FR 56935).

In response to commenters that recommended clinical superiority of new renal dialysis drugs and biological products, we explained in the CY 2019 ESRD PPS final rule (83 FR 56938) that we believed allowing all new drugs and biological products to be eligible for the TDAPA would enable new drugs and biological products to compete with other drugs and biological products in the market, which could mean lower prices for all such products. We also noted our belief that categorically limiting or excluding any group of drugs from the TDAPA would reduce the competitiveness because there would be less incentive for manufacturers to develop lower-priced drugs, such as generic drugs and biosimilar biological products, to be able to compete with higher priced drugs during the TDAPA period. In addition, we noted the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic pre-disposition and comorbidities. We stated that innovation can provide options for those patients who do not respond to a certain preferred treatment regimen the same way the majority of patients respond.

In response to commenters who recommended that we not apply the TDAPA to generic drugs and biosimilar biological products, we explained in the CY 2019 ESRD PPS final rule (83 FR 56938) that the purpose of this policy is to foster a competitive marketplace in which all drugs within a functional category would compete for market share. We stated that we believed including generic drugs and biosimilar biological products under the TDAPA expansion would mitigate or discourage high launch prices. We further explained that we believed including these products would foster innovation of drugs within the current functional categories. We also noted that we believed including these products would give a financial boost to support their utilization, and ultimately lower overall drug costs since these products generally have lower prices. Because of this, we stated that we believed that generic drugs and biosimilar biological products would provide cost-based competition for new higher priced drugs during the TDAPA period and also afterward when they are bundled into the ESRD PPS.

In response to ESRD facilities that expressed concern regarding operational difficulties and patient access issues experienced for current drugs paid for using the TDAPA, we elected to make all of the changes to the drug designation process under § 413.234 and the expansion of the TDAPA eligibility effective January 1, 2020, as opposed to January 1, 2019, to address as many of those concerns as possible (83 FR 56937). We explained in the CY 2019 ESRD PPS final rule that the additional year would provide us with the opportunity to address issues such as transitioning payment from Part D to Part B, coordinating issues involving Medicaid and new Medicare Advantage policies, and working with the current HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new drugs and biological products. We also indicated that the additional year would allow more time for ESRD facility and beneficiary education about this new policy.

In addition, with regard to the HCPCS process, we explained the additional year would help us operationally in working with the HCPCS workgroup that manages the HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new renal dialysis drugs and biological products. We explained that in collaboration with the HCPCS workgroup we would make the determination of whether a drug or biological product is a renal dialysis service. We would also determine if the new renal dialysis drug or biological product falls within an existing functional category or if it represents a new functional category (83 FR 56937 through 56938).

With regard to our proposal to not modify the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing ESRD PPS functional categories, we explained that we believe the intent of the TDAPA for these products is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new product. We further explained that we did not believe it would be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories and that doing such would be in conflict with the fundamental principles of a PPS.

We also explained that the proposal would strike a balance of maintaining the existing functional category scheme of the drug designation process and not adding dollars to the ESRD PPS base rate when the base rate may already reflect costs associated with such services, while still supporting high-value innovation and allowing facilities to adjust or factor in new drugs through a short-term transitional payment.

We stated in the CY 2019 ESRD PPS final rule (83 FR 56940) that under our final policy, beginning January 1, 2020, for new renal dialysis drugs and biological products that fall within an existing functional category, the application of the TDAPA will begin with the effective date of subregulatory billing guidance and end 2 years from that date.

For new renal dialysis drugs and biological products that do not fall within an existing functional category, we continued the existing policy that application of the TDAPA will begin with the effective date of subregulatory billing guidance and end after we determine through notice-and-comment rulemaking how the drug will be recognized in the ESRD PPS bundled payment.

Fourth, in the CY 2019 ESRD PPS final rule, we changed the TDAPA's basis of payment (83 FR 34314 through 34316). We explained that if we adopted the proposals to expand the TDAPA eligibility criteria using the current basis of payment for the TDAPA—the pricing methodologies available under section 1847A of the Act—Medicare expenditures would increase, which would result in increases of cost sharing for ESRD beneficiaries, since we had not previously provided the TDAPA for all new renal dialysis drugs and biological products. We also discussed other reasons why we believed it may not be appropriate to base the TDAPA strictly on section 1847A of the Act methodologies (83 FR 34315).

Therefore, we proposed to base the TDAPA on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6). For circumstances when ASP data is not available, we proposed that the TDAPA would be based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the TDAPA would be based on the drug manufacturer's invoice.

In the CY 2019 ESRD PPS final rule (83 FR 56943 through 56948), we discussed several comments received on this proposal. MedPAC supported the proposal to use ASP+0, stating that the ESRD PPS accounts for storage and administration costs and that ESRD facilities do not have acquisition price variation issues when compared to physicians. Conversely, industry stakeholders recommended the basis of payment remain at ASP+6 since they believe it assists with the administrative costs of packaging, handling, and staff. Commenters also recommended that CMS consider the impact of bad debt recovery and sequestration on payment when determining the basis of payment.

After considering public comments, in the CY 2019 ESRD PPS final rule (83 FR 56948), we finalized the policy as proposed, with one revision to change the effective date to CY 2020, and another revision to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We explained that we believed ASP+0 is reasonable for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also explained that we believed ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56946).

Fifth and finally, in the CY 2019 ESRD PPS final rule (83 FR 56948 through 56949), we finalized a policy to extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. Specifically, beginning January 1, 2020, if a new renal dialysis drug or biological product as defined in § 413.234(a) is considered to be a composite rate drug or biological product and falls within an existing ESRD PPS functional category, it will be eligible for the TDAPA.

We explained that we believed by allowing all new renal dialysis drugs and biological products to be eligible for the TDAPA, we would provide an ability for a new drug to compete with other similar drugs in the market which could mean lower prices for all drugs. We further explained that we believed that new renal dialysis composite rate drugs and biological products could benefit from this policy as well. Additionally, we explained that we continue to believe that the same unique consideration for innovation and cost exists for drugs that are considered composite rate drugs. That is, the ESRD PPS base rate dollars allocated for these types of drugs may not directly address the costs associated with drugs in this category when they are newly launched and are finding their place in the market. We noted that we had not

proposed to change the outlier policy and therefore these products will not be eligible for an outlier payment after the TDAPA period.

b. Basis for Refinement of the TDAPA Eligibility Criteria

In the CY 2020 ESRD PPS proposed rule (84 FR 38337 through 38339), we explained that based on feedback received during and after the CY 2019 ESRD PPS rulemaking, we were proposing to make further refinements to the TDAPA eligibility criteria. As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56935) and in section II.B.1.a of this final rule, we received many comments from all sectors of the dialysis industry and other stakeholders on our proposal in the CY 2019 ESRD PPS rulemaking to expand the TDAPA eligibility to all new renal dialysis drugs and biological products, and each had their view on the direction the policy needed to go to support innovation. We noted in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that commenters generally agreed that more drugs and biological products should be eligible for the TDAPA, that is, they agreed that drugs and biological products that fall within an ESRD PPS functional category should be eligible for a payment adjustment when they are new to the market. However, we noted that commenters also had specific policy recommendations for each element of the drug designation process, including which drugs should qualify for the TDAPA.

We also noted in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that in the CY 2019 ESRD PPS final rule (83 FR 56938) some commenters recommended that CMS not apply the TDAPA to generic drugs or to biosimilar biological products. These commenters explained that they believe the rationale for the TDAPA is to allow the community and CMS to better understand the appropriate utilization of new products and their pricing. We also noted that commenters asserted that generic drugs and biosimilar biological products seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Thus, they expressed that the additional time for uptake is unnecessary for these drugs and biological products.

In addition, we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that a drug manufacturer had commented on the CY 2019 TDAPA proposal (83 FR 56938) that a generic drug is not innovative because it must have the same active ingredient, strength, dosage form, and route of administration as the innovator drug it references in its abbreviated new drug application (ANDA). The drug manufacturer further stated that a biosimilar biological product is not innovative because it is required under the Public Health Service Act (the PHS Act) to be highly similar and have no clinically meaningful differences to the reference product and cannot be licensed for a condition of use that has not been previously approved for the reference product or for a dosage form, strength, or route of administration that differs from that of the reference product. We noted that the commenter stated that because they have no clinically meaningful differences, biosimilar biological products and reference products should be treated equally in payment and coverage policies; a biosimilar biological product should not be eligible for the TDAPA when its reference product would not qualify for the payment.

We further explained in the CY 2020 ESRD PPS proposed rule (84 FR 38338), that some commenters on the CY 2019 TDAPA proposal recommended that CMS require that the new renal dialysis drug or biological product have a clinical superiority over existing drugs in the ESRD PPS bundled payment in order to be eligible for the TDAPA, and provided suggestions on clinical value criteria. We stated that a dialysis facility organization expressed concern that the proposed policy would encourage promotion of so called ''me too'' drugs and higher launch prices, even if moderated after 2 years. We noted that a drug manufacturer recommended that CMS consider when FDA may re-profile a drug and that the commenter further explained that re-profiling a drug may occur when its utility and efficacy are further elucidated or expanded once on-market. We also noted that the commenter recommended that CMS establish a pathway as part of the drug designation process that would allow for manufacturers or other stakeholders to request that CMS reconsider how a particular drug is classified with regard to the functional categories.

In the CY 2020 ESRD PPS proposed rule (84 FR 38338) we discussed MedPAC's comment from the CY 2019 ESRD PPS final rule (83 FR 56936). MedPAC had recommended that CMS not proceed with its proposal to apply the TDAPA policy to new renal dialysis drugs that fit into an existing functional category for several reasons. For example, MedPAC stated that paying the TDAPA for new dialysis drugs that fit into a functional category would be duplicative of the payment that is already made as part of the ESRD PPS bundle. MedPAC also asserted that applying the TDAPA to new dialysis drugs that fit into an existing functional category undermines competition with existing drugs included in the PPS payment bundle since the TDAPA would effectively unbundle all new dialysis drugs, removing all cost constraints during the TDAPA period and encouraging the establishment of high launch prices.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that since publishing the CY 2019 ESRD PPS final rule, we have continued to hear concerns about expanding the TDAPA policy from numerous stakeholders, including ESRD facilities and their professional associations, beneficiaries and their related associations, drug manufacturers, and beneficiary groups.

We also stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338), that our data contractor held a Technical Expert Panel (TEP) in December 2018, and gathered input regarding the expanded TDAPA policy at that time. More information about the TEP is discussed in section VIII.A of the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), and in section VIII.A of this final rule. We noted that some ESRD facility associations participating in the TEP generally expressed concern that the TDAPA policy, as finalized in the CY 2019 ESRD PPS final rule, would inappropriately direct Medicare dollars to drugs and biological products that may be new to the market but not new with regard to certain characteristics of the drug itself. For example, commenters noted that section 505 of the FD&C Act is broad and includes FDA approval of a new drug application (NDA), which is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the U.S.[1] We explained that section 505 of the FD&C Act, which includes sections 505(b)(1) and (b)(2) and 505(j) for generic drugs, includes FDA approval of NDAs for drugs that have a new dosage form, a reformulation, or a re-engineering of an existing product and that some of these types of drugs are referred to in the pharmaceutical industry as line extensions, follow-on products, or me-too drugs.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that due to the feedback received following publication of the CY 2019 ESRD PPS final rule, we had continued to analyze certain aspects of the policies finalized

[1] FDA. New Drug Application (NDA). Available at: *https://www.fda.gov/drugs/types-applications/new-drug-application-nda*.

in the CY 2019 ESRD PPS final rule and therefore we were revisiting those issues as part of that rule. Specifically, since ESRD facilities and other dialysis stakeholders have expressed concern about the broad nature of including all new renal dialysis drugs and biological products as eligible for the TDAPA, we were reconsidering whether all new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category should be eligible for the TDAPA.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that in the CY 2019 ESRD PPS final rule (83 FR 56932) we finalized that effective January 1, 2020, a new renal dialysis drug or biological product is defined in § 413.234 as ''[a]n injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the FDA on or after January 1, 2020, under section 505 of the [FD&C Act] or section 351 of the [PHS Act], commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.'' We noted that while there are several parts of this definition, in the proposed rule we focused on the requirement that the product be approved by FDA ''under section 505 of the [FD&C Act] or section 351 of the [PHS Act].'' Specifically, we proposed that certain new renal dialysis drugs approved by FDA under those authorities would not be eligible for the TDAPA under § 413.234(c)(1).

We explained in the CY 2020 ESRD PPS proposed rule (84 FR 38338 through 38339) that section 505 of the FD&C Act and section 351 of the PHS Act provide the authority to FDA for approving drugs and biological products, respectively, and provide several pathways for drug manufacturers to submit NDAs and biologics license applications (BLAs). We noted that we have consulted with FDA and studied the different categories of NDAs and the different biological product pathways to consider whether the full breadth of these authorities aligned with our goals for the TDAPA policy under the ESRD PPS. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56935), the purpose of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category is to support innovation and help ESRD facilities to incorporate new products and make appropriate changes in their businesses to adopt such products; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories.

We explained that FDA approves certain new drugs under section 505(c) of the FD&C Act, which includes NDAs submitted pursuant to section 505(b)(1) or 505(b)(2) of the FD&C Act. We further explained that section 505(b)(1) of the FD&C Act is a pathway for ''stand-alone'' applications and is used for drugs that have been discovered and developed with studies conducted by or for the applicant or for which the applicant has a right of reference, and are sometimes for new molecular entities and new chemical entities that have not been previously approved in the U.S.

We also explained that section 505(b)(2) of the FD&C Act is another pathway for NDAs, where at least some of the information for an approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) application may rely on FDA's finding of safety and/or effectiveness for a listed drug (an approved drug product) or published literature provided that such reliance is scientifically justified and the 505(b)(2) applicant complies with the applicable statutory and regulatory requirements, including patent certification if appropriate. (See section 505(b)(2) of the FD&C Act and 21 CFR 314.54.) NDAs submitted pursuant to section 505(b)(1) or 505(b)(2) of the FD&C Act are divided into categories by FDA.

We explained in the CY 2020 ESRD PPS proposed rule (84 FR 38339) that the Office of Pharmaceutical Quality in FDA's Center for Drug Evaluation and Research (CDER) has an NDA categorizing system that utilizes NDA Classification Codes. As explained in FDA/CDER Manual of Policies and Procedures (MAPP) 5018.2, ''NDA Classification Codes'', the codes evolved from both a management and a regulatory need to identify and group product applications based on certain characteristics, including their relationships to products already approved or marketed in the U.S. FDA tentatively assigns an NDA Classification Code (that is, Type 1 NDA through Type 10 NDA) by the filing date for an NDA and reassesses the code at the time of approval. The reassessment is based upon relationships of the drug product seeking approval to products already approved or marketed in the U.S. at the time of approval. FDA may also reassess the code after approval. We stated that the NDA Classification Codes are not necessarily indicative of the extent of innovation or therapeutic value that a particular drug represents. More information regarding the NDA Classification Codes is available in FDA/CDER MAPP 5018.2 on FDA website at: *https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm470773.pdf* and summarized in Table 1.

TABLE 1—NDA CLASSIFICATION CODES

Classification	Meaning
Type 1	New molecular entity.
Type 2	New active ingredient.
Type 3	New dosage form.
Type 4	New combination.
Type 5	New formulation or other differences.
Type 6	New indication or claim, same applicant [no longer used].
Type 7	Previously marketed but without an approved NDA.
Type 8	Prescription to Over-the-Counter.
Type 9	New indication or claim, drug not to be marketed under type 9 NDA after approval.
Type 10	New indication or claim, drug to be marketed under type 10 NDA after approval.
Type ¼	Type 1, New molecular entity, and Type 4, New combination.
Type ⅔	Type 2, New active ingredient, and Type 3, New dosage form.
Type ¾	Type 2, New active ingredient and Type 4, New combination.
Type ¾	Type 3, New Dosage Form, and Type 4, New combination.

We further explained in the CY 2020 ESRD PPS proposed rule (84 FR 38339) that an ANDA is an application submitted by drug manufacturers and approved by FDA under section 505(j) of the FD&C Act for a ''duplicate'' [2] of a previously approved drug product. We noted that ANDAs are used for generic drugs and rely on FDA's finding that the previously approved drug product, that is, the reference listed drug, is safe and effective.

We stated that biological products are licensed by FDA under section 351 of the PHS Act. Section 351(a) of the PHS Act is the pathway for ''stand-alone BLAs'' that contain all information and data necessary to demonstrate that (among other things) the proposed

[2] The term *duplicate* generally refers to a ''drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as a listed drug,'' as a previously approved drug product. See 54 FR 28872 (July 10, 1989). An exception to this general rule is that FDA may approve ANDAs with certain changes from a listed drug regarding active ingredient, dosage form, strength, and route of administration if a ''suitability petition'' has been approved under section 505(j)(2)(C) of the FD&C Act.

biological product is safe, pure and potent. The 351(k) BLA pathway requires that the application contain information demonstrating that the biological product is biosimilar to or interchangeable with an FDA-licensed reference product. We noted that FDA does not assign classification codes for BLAs like it does for NDAs.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38339) that in addition to consulting with FDA, pharmaceutical statisticians within CMS have provided insight on the potential outcomes of providing payment incentives for promoting competition among drugs and biological products within the ESRD PPS functional categories. Specifically, we learned that certain unintended consequences could arise from providing payment incentives for drugs with innovative qualities (for example, new molecular entities) in the same way as drugs with non-innovative qualities (for example, generic drugs). For example, more attention might be diverted to the less costly duplication of drugs that are already available rather than those that may be more expensive to develop and bring to market. We noted that we believed this could cause an influx of non-innovative drugs to the dialysis space, potentially crowding out innovative drugs.

c. Proposed Refinement of the TDAPA Eligibility Criteria

In the CY 2020 ESRD PPS proposed rule (84 FR 38339 through 38340) we explained that we analyzed the information we gathered since publishing the CY 2019 ESRD PPS final rule and contemplated the primary goal of the TDAPA policy for new renal dialysis drugs and biological products that fall within ESRD PPS functional categories, which is to support innovation and encourage development of these products. We stated that we believed this is accomplished by providing an add-on payment adjustment to ESRD facilities during the uptake period for a new renal dialysis drug or biological product to help the facilities incorporate new drugs and make appropriate changes in their businesses to adopt such drugs. We also noted that the TDAPA provides additional payment for costs associated with these changes.

We stated that in addition to supporting innovation, we were mindful of the increase in Medicare expenditures associated with the expanded TDAPA policy. We noted that the first year in which we paid the TDAPA, CY 2018, resulted in an estimated $1.2 billion increase in ESRD PPS expenditures for two calcimimetic drugs used by approximately 25 percent of the Medicare ESRD population. We recognized that the policy we finalized in the CY 2019 ESRD PPS final rule would mean that each new renal dialysis drug and biological product eligible for the TDAPA would result in an increase in Medicare expenditures. However, we noted that we were balancing an increase in Medicare expenditures with the rationale for fostering a competitive marketplace. We noted that in the CY 2019 ESRD PPS final rule (83 FR 56937), we stated our belief that by expanding the eligibility for TDAPA to all new drugs and biological products we would promote competition among drugs and biological products within the ESRD PPS functional categories, which could result in lower prices for all drugs.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38340) that in response to ESRD facility and other dialysis stakeholders' concerns raised during and after the CY 2019 ESRD PPS rulemaking, and after conducting a closer study of FDA's NDA process, we were reconsidering the eligibility criteria that we finalized effective January 1, 2020. Since there are not unlimited Medicare resources, we stated that we believed those resources should not be expended on additional payments to ESRD facilities for drugs and biological products that are not truly innovative, and that such additional payments may facilitate perverse incentives for facilities to choose new products simply for financial gain. We also noted that we believed that since we have the ability to be more selective, through FDA's NDA Classification Codes, with the categories of renal dialysis drugs that would be eligible for the TDAPA for products in existing ESRD PPS functional categories, we can balance supporting innovation, incentivizing facilities with uptake of new and innovative renal dialysis products, and fostering competition for renal dialysis drugs and biological products that are new and innovative, rather than just new.

We acknowledged that the definition finalized in the CY 2016 ESRD PPS final rule (80 FR 69015 through 69027), which includes products ''approved by [FDA] . . . under section 505 of the [FD&C Act] or section 351 of the [PHS Act]'' has been part of the TDAPA eligibility criteria since the inception of the policy. We also acknowledged that this may be too expansive for purposes of determining eligibility for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category. For example, there may be new renal dialysis drugs approved by FDA under section 505 of the FD&C Act that may not be innovative.

We also acknowledged that while dialysis industry stakeholders recommended that we adopt significant clinical improvement standards for the TDAPA eligibility, we believed that unlike many Medicare beneficiaries, the Medicare ESRD beneficiary is significantly complex, with each patient having a unique and challenging profile for medical management of drugs and biological products. We stated that we believed that practitioners should have the opportunity to evaluate the appropriate use of a new drug or biological product and its effect on patient outcomes and interactions with other medications the patient is currently taking. We further noted that the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic pre-disposition and comorbidities. We stated that we believed that innovation of drugs and biological products can provide options for those patients who do not respond to a certain preferred treatment regimen the same way the majority of patients respond.

Therefore, in the CY 2020 ESRD PPS proposed rule (84 FR 38341 through 38344) we discussed categories of drugs that we proposed to exclude from eligibility for the TDAPA and our proposed revisions to the drug designation process regulation in § 413.234 to reflect those categories.

We also proposed to rely on, as a proxy, the NDA Classification Code, as it exists as of November 4, 2015, which is part of FDA/CDER MAPP 5018.2 (84 FR 38340). The FDA/CDER MAPP 5018.2 is available at FDA website *https://www.fda.gov/media/94381/download*. We recognized that FDA's NDA Classification Codes do not necessarily reflect the extent of innovation or therapeutic advantage that a particular drug product represents. However, we stated that we believed FDA's NDA Classification Codes would provide an objective basis that we can use to distinguish innovative from non-innovative renal dialysis service drugs. We noted that we believed that distinguishing drugs would help us in our effort to support innovation by directing Medicare resources to renal dialysis drugs and biological products that are not reformulations or new dosage forms, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that

advance the treatment for ESRD beneficiaries at a lower cost.

We stated that the classification code assigned to an NDA generally describes FDA's classification of the relationship of the drug to drugs already marketed or approved in the U.S. We proposed that if FDA makes changes to the NDA Classification Codes in FDA/CDER MAPP 5018.2, we would assess FDA changes at the time they are publicly available and we would analyze those changes with regard to their implications for the TDAPA policy under the ESRD PPS (84 FR 38340). We stated that we would plan to propose in the next rulemaking cycle, any necessary revisions to the exclusions set forth in proposed § 413.234(e). We solicited comment on the proposal to rely on, as a proxy, the NDA Classification Codes, as it exists as of November 4, 2015, which is part of the FDA/CDER MAPP 5018.2. We also solicited comments on the proposal that we would assess FDA changes to the NDA Classification Codes at the time they are publicly available to analyze the changes with regard to their implications for the TDAPA policy and propose in the next rulemaking cycle, any necessary revisions to the proposed exclusions.

We explained in the CY 2020 ESRD PPS proposed rule (84 FR 38340) that currently, stakeholders must notify the Division of Chronic Care Management in our Center for Medicare of the interest for eligibility for the TDAPA and provide the information requested (83 FR 56932) for CMS to make a determination as to whether the new renal dialysis drug or biological product is eligible for the adjustment. We stated that, with regard to operationalizing the proposed exclusions, in addition to the information currently described on the CMS ESRD PPS TDAPA web page under the Materials Required for CMS Determination Purposes,[3] we would request that the stakeholder provide the FDA NDA Type classified at FDA approval or state if the drug was approved by FDA under section 505(j) of the FD&C Act. We explained that if the FDA NDA Type assigned at FDA approval changes subsequently to the submission of the TDAPA application into CMS, we would expect that the submitter would resubmit the TDAPA request, and we would re-evaluate the submission. We noted that we plan to have quarterly meetings with FDA to discuss new renal dialysis drugs and biological products that are eligible for the TDAPA.

We stated that, as discussed in the CY 2019 ESRD PPS final rule (83 FR 56932), once the information requested by CMS is received and reviewed, for new renal dialysis drugs and biological products eligible for the TDAPA, we will issue a change request with billing guidance that will provide notice that the product is eligible for the TDAPA as of a certain date and guidance on how to report the new drug or biological product on the ESRD claim. We noted that the effective date of this change request will initiate the TDAPA payment period and, for drugs that do not fall within a functional category, the data collection period.

We also noted that for new renal dialysis drugs and biological products that are not eligible for the TDAPA, we will issue a change request that will provide notice that the drug is included in the ESRD PPS base rate, qualifies as an outlier service, and is available for use, to help ensure patients have access to the new product.

i. Proposed Exclusions From the TDAPA Eligibility

In the CY 2020 ESRD PPS proposed rule (84 FR 38341 through 38343), using the current categories in FDA/CDER MAPP 5018.2 effective November 4, 2015, we proposed to exclude Types 3, 5, 7 and 8, Type 3 in combination with Type 2 or Type 4, Type 5 in combination with Type 2, and Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8 from being eligible for the TDAPA under § 413.234(b)(1)(ii) and § 413.234(c)(1). A Type 9 NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the ''parent NDA''), and the applicant does not intend to market this drug product under the Type 9 NDA after approval. We explained that we would use the NDA Classification Codes Type identified at FDA approval. If FDA changes the classification code Type after we start applying the TDAPA with respect to a particular new renal dialysis drug, we would re-evaluate TDAPA eligibility. We also proposed to exclude generic drugs from being eligible for the TDAPA under § 413.234(b)(1)(ii) and § 413.234(c)(1).

In the following paragraphs we provide our description from the CY 2020 ESRD PPS proposed rule of each NDA Type, also referred to as NDA Classification Codes, and generic drugs that we proposed for exclusion and give our justifications for proposing that these products should not be eligible for the TDAPA for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category.

(a) Type 3 NDA—New Dosage Form

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38341), some dialysis stakeholders expressed concern that we would be paying the TDAPA for changes that did not reflect a product being significantly innovative, such as a pill size, pill scoring, oral solutions and suspensions of drugs that were previously only approved as solid oral dosage forms, time-release forms, chewable or effervescent pills, orally disintegrating granules or adsorptive changes, or routes of administration. In response to these concerns, we proposed to exclude Type 3 NDAs, which is for a new dosage form of an active ingredient that has been approved or marketed in the U.S. by the same or another applicant but has a different dosage form, as well as Type 3 in combination with Type 2 or Type 4, from being eligible for the TDAPA under § 413.234(b)(1)(ii). In addition, we proposed to exclude Type 9 NDAs, as discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), when the ''parent NDA'' is a Type 3 NDA.

We explained that FDA's regulation defines an active ingredient as a component of the drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (21 CFR 314.3(b), which is incorporated in FDA/CDER MAPP 5018.2).

We also explained FDA's regulation defines dosage form as the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product (21 CFR 314.3(b), which is incorporated in FDA/CDER MAPP 5018.2). This includes such factors as: (1) The physical appearance of the drug product, (2) the physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, and (4) the design features that affect the frequency of dosing.

We further stated that for Type 3 NDA drugs, the indication does not need to be the same as that of the already approved drug product. Once the new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as Type 5 NDA.

We noted that we believed that for purposes of the ESRD PPS, we do not want to incentivize the use of one

[3] CMS. ESRD PPS Transitional Drug Add-on Payment Adjustment. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.*

dosage form of the drug over another. Even though the original product may be innovative, we would not consider making that product into a new dosage form to be innovative for purposes of the ESRD PPS. Although these drugs may provide an expansion of patient treatment options, we believed these changes are not innovative and these drugs should not be paid for using the TDAPA. We stated these drugs are still accounted for in the ESRD PPS base rate and would be eligible for an outlier payment. We noted that this type of research, development and marketing activity has been termed ''product hopping'' and can help manufacturers prolong revenue streams.[4] We stated that we did not believe these products should be eligible for the TDAPA because we did not want to provide perverse incentives for facilities to choose a new dosage form in order to obtain the TDAPA. In addition, we did not want to encourage the practice of companies moving drug research and development dollars from one branded drug to another, very similar drug with a longer patent life, thus increasing its market exclusivity for many years. We noted that we believed that this practice was counter to our goal of not only increasing competition among drugs in the ESRD functional categories so there are better drugs at lower cost, but also making the best use of Medicare resources and directing of those resources to payment for the utilization of high value, innovative drugs. For these reasons, we proposed to exclude Type 3 NDA drugs from being eligible for the TDAPA.

(b) Type 5 NDA—New Formulation or Other Differences

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), we proposed to exclude Type 5 NDA drugs, which can be a new formulation or new manufacturer, from being eligible for the TDAPA. In addition, we proposed to exclude Type 9 NDAs, when the ''parent NDA'' is a Type 5 NDA. We noted that drugs that are classified as a Type 5 NDA are sometimes referred to as reformulations or follow-on products. We explained that a Type 5 NDA is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the seven following product characteristics.

The first characteristic involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and the product is submitted as an original NDA rather than as a supplement by the applicant of the approved product.

The second characteristic is that the product is a ''duplicate'' of a drug product by another applicant same active ingredient, same dosage form, same or different indication, or same combination, and requires one of the following 4 items: (a) Bioequivalence testing, including bioequivalence studies with clinical endpoints, but is not eligible for submission as a section 505(j) application; (b) safety or effectiveness testing because of novel inactive ingredients; (c) full safety or effectiveness testing because the product is one of the following four items: (i) Is subject to exclusivity held by another applicant; (ii) is a product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, (iii) it is a crude natural product, or, (iv) it is ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability, for example, products with different release patterns or (d) the applicant has a right of reference to the application.

The third characteristic is that the product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. We explained that this applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources. We also explained that an active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance (21 CFR 314.3(b)).

The fourth characteristic is that the product is a combination product that differs from a previous combination product by removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one of more of the active ingredients. We explained that in the case of a substitution of a noncovalent derivative of an active ingredient for one or more of the active ingredients, the NDA would be classified as a Type 2, 5 combination and we proposed to exclude it from eligibility for the TDAPA under § 413.234(b)(1)(ii).

The fifth characteristic is that the product contains a different strength of one or more active ingredients in a previously approved or marketed combination. We explained that a Type 5 NDA would generally be submitted by an applicant other than the holder of the approved application for the approved product. We also explained that a similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

The sixth characteristic is that the product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an ANDA under section 505(j) of the FD&C Act.

The seventh characteristic is that the product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, Parenteral drugs in plastic containers, and FDA/CDER MAPP 6020.2, Applications for Parenteral Products in Plastic Immediate Containers).

In the CY 2020 ESRD PPS proposed rule (84 FR 38342 through 38343) we noted that some commenters have characterized the types of drugs that are often approved in Type 5 NDAs as reformulations or line extensions. We explained that a line extension is a variation of an existing product.[5] The variation can be a new formulation (reformulation) of an existing product, or a new modification of an existing molecular entity.[6] We further explained that a line extension has been defined as a branded pharmaceutical product that: (1) Includes the same active ingredient (either alone or in combination with other active ingredients) as an original product, (2) is manufactured by the same drug manufacturer that makes the original product, or by one of its partners or subsidiaries, and (3) is launched after the original product.[7] An NME is discussed in section II.B.1.c.ii.(a) of this final rule. We noted that line extensions were few in number prior to 1984, when the Drug Price Competition and Patent Term Restoration Act was passed

[4] Reed F. Beall et al. New Drug Formulations and Their Respective Generic Entry Dates, JMCP. February, 2019, 25(2): 218–224. Available at: *https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218.*

[5] V Kadiyali et al. Product line extensions and competitive market interactions: An empirical analysis. J Econometrics. 1998, 89 (1–2): 339–63.

[6] SH Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, J MCP. 2005, 11(9): 746–754.

[7] AC Fowler, October 6, 2017, White Paper—Pharmaceutical Line Extensions in the United States, *http://www.nber.org/aging/valmed/WhitePaper-Fowler10.2017.pdf.*

following public outcry over high drug prices and rising drug expenditures, and following passage of that law, line extensions became prevalent in the pharmaceutical drug industry. We also noted that we were aware that one of the acknowledged criticisms of pharmaceutical line extensions is their use as a strategy to extend the patent protections for products that have patents that are about to expire, by developing a new formulation and taking out new patents for the new formulation.[8] We stated that it has been noted that line extensions through new formulations are not being developed for significant therapeutic advantage, but rather for the company's economic advantage.[9]

We explained that we did not believe the characteristics of Type 5 NDA drugs would advance the intent of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category. We noted that we believed that while Type 5 NDA drugs may have clinical benefits to patients over previously approved products, we did not make that assessment as part of ESRD PPS payment policy. We stated that we did not believe the types of changes represented by Type 5 NDAs enhance our goal of increased competition with the overarching goal of lowering drug prices. We noted that to the contrary, it seems that a goal of line extensions can be to thwart competition. We also noted that studies indicate that there is no lowering of prices through competition from line extensions. Rather, it has been reported that prices remain rigid and are not lowered. In fact, not only can product line extensions thwart competition, but they inherit the market success of the original brand, sometimes with little quality improvement over the original brand.[10] For these reasons, we explained that we did not believe providing a payment adjustment to ESRD facilities to support the uptake of a drug that is a line extension in their business model is a judicious use of Medicare resources.

We noted that a study published in February 2019, concluded that the pattern of a considerable subset of reformulations prolonged the consumption of costly brand-name products at the expense of timely market entry of low cost generics.[11] We also noted that this and other recent publications this past year have been helpful to inform policy proposals by demonstrating that reformulations frequently kept drug prices high, which does not meet our goal of increased competition assisting in the lowering of drug prices, at the expense of Medicare resources being directed to innovative drugs that advance the treatment of ESRD. Consequently, we noted that we believed it was important to propose to install guardrails to ensure that sufficient incentives exist for timely innovative drugs for the ESRD patients, that competition for lowering drug prices is not thwarted, and that perverse incentives do not exist for patients to receive a drug because it is financially rewarding, through the TDAPA, for the ESRD facilities. For these reasons, we stated that we did not believe Type 5 NDA drugs should be eligible for the TDAPA, and we proposed to exclude them in new § 413.234(e).

(c) Type 7 NDA—Previously Marketed but Without an Approved NDA

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), we proposed to exclude Type 7 NDA, which is for a drug product that contains an active moiety that has not been previously approved in an application but has been marketed in the U.S., from being eligible for the TDAPA for renal dialysis drugs and biological products in existing functional categories. In addition, we proposed to exclude Type 9 NDAs when the ''parent NDA'' is a Type 7 NDA. We explained that this classification only applies to the first NDA approved for a drug product containing this (these) active moiety(ies). They include, but are not limited to the following four items: (1) The first post-1962 application for an active moiety marketed prior to 1938; (2) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation (DESI) notice (FDA's regulation at 21 CFR 310.6(b)(1) states that, ''[a]n identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties''); (3) The first application for an IRS drug product first marketed after 1962; and (4) The first application for an active moiety that was first marketed without an NDA after 1962.

We stated that we did not believe the characteristics of Type 7 NDA drugs would advance the intent of the TDAPA policy because these drugs were already on the market. For example, FDA received an application for calcium gluconate, which is on the Consolidated Billing List and is already recognized as a renal dialysis service included in the ESRD PPS base rate. The NDA for calcium gluconate was classified by FDA in 2017 to be a Type 7 NDA. We stated that we believed this drug was not innovative and does not significantly advance the treatment options for ESRD. We also noted that we believed that if the Type 7 NDA drug is determined to be a renal dialysis service, it is likely it is already being used by the facility, so paying the TDAPA for it does not assist the facilities in uptake for their business model, which is one of the goals of the TDAPA. In addition, we stated that we believed paying the TDAPA for Type 7 NDA drugs uses Medicare resources that ultimately could be used to pay for innovative drugs and services that result from research and development in areas of high value innovation. Therefore, we did not consider Type 7 NDA drugs to be eligible for the TDAPA.

(d) Type 8 NDA—Prescription to Over-the-Counter (OTC)

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), we proposed to exclude Type 8 NDA, which is when a prescription drug product changes to an over-the-counter (OTC) drug product, from being eligible for the TDAPA. In addition, we proposed to exclude Type 9 NDAs when the ''parent NDA'' is a Type 8 NDA. We explained that a Type 8 NDA is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription. We further explained that a Type 8 NDA may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

We explained that if the proposed OTC switch would apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), then FDA indicates that the application holder should submit the change as a supplement to the approved application. We noted that if the

[8] SH Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, J MCP. 2005, 11(9): 746–754.

[9] R Collier Drug patents: The evergreening problem. CMAJ. 2013 Jun11; 185(9):E385–6. doi: 10.1503/cmaj.109–4466. Epub 2013 Apr 29.

[10] SH Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, J MCP. 2005, 11(9): 746–754.

[11] Reed F. Beall et al. New Drug Formulations and Their Respective Generic Entry Dates, JMCP. February, 2019, 25(2): 218–224. Available at: *https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218*.

applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), FDA indicates that the applicant should submit a new NDA for the OTC products, which would be classified as Type 8 NDA.

We stated that we did not believe the characteristics of Type 8 NDA drugs would advance the intent of the TDAPA policy for renal dialysis drugs and biological products in existing functional categories because Type 8 NDAs are for drugs transitioning from prescription to OTC, and Medicare does not provide coverage of OTC drugs. We noted that we believed that although certain innovative approaches may help increase access to a broader selection of nonprescription drugs for ESRD beneficiaries, we did not consider the transition from prescription to OTC to be innovative for purposes of the TDAPA policy. We stated that we believed making the TDAPA available for Type 8 NDAs may defeat the intent of lowering overall costs for both the ESRD beneficiary and for Medicare, and was not needed by the facilities to provide additional support during an uptake period so they can be incorporated into the business model. We noted that OTC drugs have already gone through safety trials if they were previously prescription drugs and their end-point physiologic activity had been recognized and documented. Therefore, we stated that we believed the newness is a reflection of accessibility to the general public without having to obtain a prescription through a licensed practitioner. We noted that we believed these drugs, though new to the market, are not sufficiently innovative to qualify for TDAPA eligibility.

(e) Generic Drugs

We proposed to exclude drugs approved by FDA under section 505(j) of the FD&C Act, which are generic drugs, from being eligible for the TDAPA. As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38337 through 38339), an ANDA is an application submitted by drug manufacturers and approved by FDA under section 505(j) of the FD&C Act for a duplicate of a previously approved drug product.

We explained that an ANDA generally must contain information to show that the proposed generic product: (1) Is the same as the reference listed drug (RLD) with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) and (2) is bioequivalent to the RLD. See section 505(j)(2)(A) of the FD&C Act. In general, an ANDA would not be appropriate if clinical investigations are necessary to establish the safety and effectiveness of the proposed product. A drug product approved in an ANDA is presumed to be therapeutically equivalent to its RLD. A drug product that is therapeutically equivalent to an RLD can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling.

We noted that, in the CY 2019 ESRD PPS final rule (83 FR 56931), we included generic drugs in the definition of a new renal dialysis drug or biological product eligible for the TDAPA because we believed this would foster both a competitive marketplace and innovation of drugs within functional categories, mitigate high launch prices, and provide a financial boost to support utilization. We explained that during the CY 2019 ESRD PPS rulemaking, we were aware of the pricing strategies being used by certain pharmaceutical companies to block the entry of generic drugs into the market in order to keep drug prices high. Though generic drugs are not considered innovative products, our primary intent in making generic drugs eligible for the TDAPA was to increase competition so that drug prices would be lower for the beneficiary. We then noted that we have since learned that bringing more generic drugs to market, though a significant component in lowering drug prices, is not in and of itself the solution.

We discussed a June 2018 report that examined increased generic drug competition as the primary impetus to curtail skyrocketing drug prices, and found that though it is helpful, there is a ceiling on its impact. It found that generic competition would not affect 46 percent of the estimated sales revenue of the top 100 drugs through 2023.[12]

We also discussed a June 2018 article, which noted that competition has a limited impact on American health care, particularly when it comes to expensive interventions like prescription drugs. The article noted that when an expensive drug's competition within the same family of drugs came on the market the prices did not go down. Rather, the prices increased approximately 675 percent. Each new entrant cost more than its predecessors, and their makers then increased their prices to match the newcomer's. The article stated that when the first generic finally entered the market, its list price was only slightly less at 539 percent above the original entrant. It stated that economists call this ''sticky pricing'' and the article noted that this is common in pharmaceuticals, and has raised the prices in the U.S. of drugs for serious conditions even when there are multiple competing drugs. Compounding this problem, the article stated that companies have decided it is not in their interest to compete.[13]

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38344) that for purposes of the ESRD PPS, we believed that we need to strike a balance between enhancing significant renal dialysis drug innovation and encouraging competition through support of innovative drugs that would become optimal choices for ESRD patients and advance their care through improved treatment choices. We noted that we believed that our goal in supporting competition among drugs in the ESRD PPS functional categories was to ultimately affect the launch price of new drugs. We stated that we questioned whether including all new renal dialysis drugs and biological products as eligible for the TDAPA would help us meet that goal. We expressed that reining in launch prices by placing guardrails on line extensions, reformulations and ''sticky pricing'' while staying mindful of the Medicare trust fund would better enable us to achieve our goals for the TDAPA policy.

Therefore, we proposed to revise the drug designation process regulation at § 413.234 by revising paragraph (b)(1)(ii) and adding paragraph (e), effective January 1, 2020, to specify that a new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the TDAPA if it is a generic drug or if the NDA for the drug is classified by FDA as a certain Type—specifically, if the drug is approved under section 505(j) of the FD&C Act or the NDA for the drug is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 4, or Type 5 in combination with Type 2, or Type 9

[12] B Isgur et al., Health Research Institute, The FDA is approving more generic drugs than ever before. Faster than ever before. Is it enough to lower drug costs? June 2018. Available at: *https://www.pwc.com/us/en/health-industries/health-research-institute/pdf/pwc-health-research-institute-generic-drug-pricing-june-2018.pdf.*

[13] E Rosenthal, New York Times, Why Competition Won't Bring Down Drug Prices. June 21, 2018. Available at: *https://www.nytimes.com/2018/06/21/opinion/competition-drug-prices.html.*

when the ''parent NDA'' is a Type 3, 5, 7 or 8.

We solicited comments as to whether any NDA Types that would remain eligible for the TDAPA under our proposal should be excluded, and whether any NDA Types that we proposed to exclude should be included, for example, within the NDA Type 3 (new dosage form) the inclusion of IV to oral route of administration.

ii. Examples of New Renal Dialysis Drugs and Biological Products That Would Remain Eligible for the TDAPA

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38344) that under our proposal, any new renal dialysis drug or biological product that we did not propose for exclusion, would continue to be eligible for the TDAPA. In the CY 2020 ESRD PPS proposed rule (84 FR 38344 through 38346), we provided some examples of the types of renal dialysis drugs and biological products that we believed would continue to be eligible for the TDAPA under our proposal, using the descriptions in the NDA Classification Codes referenced in the CY 2020 ESRD PPS proposed rule (84 FR 38339 through 38341). We noted that under our proposal, BLAs approved by FDA under section 351 of the PHS Act, which include biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, also would continue to be eligible for the TDAPA.

(a) Type 1 NDA—New Molecular Entity

In the CY 2020 ESRD PPS proposed rule (84 FR 38344), we explained that a Type 1 NDA refers to drugs containing an NME. We further explained that an NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505(b) of the FD&C Act or has been previously marketed as a drug in the U.S.

We stated that we believed the new renal dialysis drugs that are classified by FDA as a Type 1 NDA should continue to be eligible for the TDAPA because they generally fall within the 505(b)(1) pathway typically used for novel drugs, meaning they have not been previously studied or approved, and their development requires the sponsor to conduct all studies needed to demonstrate the safety and efficacy of the drug. We noted that unlike the drugs proposed to be excluded from the TDAPA as described above, these drugs are generally not line extensions of previously existing drugs. We stated that we believed there will be expenses with uptake by ESRD facilities of Type 1 NDA drugs, and one of the goals of the TDAPA is to provide additional support to ESRD facilities during the uptake period for these innovative drugs and help incorporate them into their business model.

(b) Type 2 NDA—New Active Ingredient

In the CY 2020 ESRD PPS proposed rule (84 FR 38344 through 38345), we explained that a Type 2 NDA is for a drug product that contains a new active ingredient, but not an NME. We further explained that a new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. Furthermore, if the active ingredient is a single enantiomer and a racemic mixture (the name for a 50:50 mixture of 2 enantiomers) containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a Type 2 NDA. Enantiomers are chiral molecules that are non-superimposable, mirror images of one another.

We stated that we believed the new renal dialysis drugs classified by FDA as Type 2 NDAs should be eligible for the TDAPA because, in part, it covers a single enantiomer active ingredient for which a racemic mixture containing that enantiomer has been approved by FDA. We noted that single enantiomer drugs can lead to fewer drug interactions in the ESRD population, which already has a significant medication burden.[14] We stated that we believed these drugs are innovative and it is important to support their development because of their lower development cost burden, coupled with enhancement of patient choice, which supports not only innovation, but the ability of the product to successfully launch and compete. We noted that we believed having the Type 2 NDA drugs be eligible for the TDAPA would support our goal of providing support to the ESRD facilities for 2 years while the drug is being incorporated into their business model.

(c) Type 4 NDA—New Combination

In the CY 2020 ESRD PPS proposed rule (84 FR 38345), we explained that a Type 4 NDA is a new drug-drug combination of two or more active ingredients. We further explained that an application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient.

We proposed that new renal dialysis drugs that are classified as a Type 4 NDA should continue to be eligible for the TDAPA if at least one of the components is a Type 1 NDA (NME) or a Type 2 NDA (new active ingredient), both of which merit the TDAPA as previously discussed. We stated that we believed that an added advantage is that while introducing an innovative product, which is not the case for Type 3 NDA drugs, it reduces the pill burden to a patient population challenged with multiple medications and a complex drug regimen. We noted that medication adherence is thought to be around 50 percent in the dialysis population and reducing this burden can improve adherence and should lead to improvement in treatment outcomes.[15]

We noted that we believed the advantages of Type 1 NDA and Type 2 NDA drugs, coupled with the possibility of improved adherence, merits eligibility for the TDAPA in that it encourages both innovators to develop competitive drugs at lower prices for this NDA Type, and ESRD facilities to use the products with the boost that the TDAPA will provide in facilitating uptake of these new products.

(d) Type 9 NDA—New Indication or Claim, Drug Not To Be Marketed Under Type 9 NDA After Approval

In the CY 2020 ESRD PPS proposed rule (84 FR 38345), we explained that a Type 9 NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the ''parent NDA''), and the applicant does not intend to market this drug product under the Type 9 NDA after approval. We explained that a Type 9 NDA is generally submitted as a separate NDA so as to be in

[14] A. Calcaterra and I. D'Acquarica, J Pharmaceutical and Biomedical Analysis, ''The market of chiral drugs: Chiral switches versus de novo enantiomerically pure compounds,'' 147(2018). Pages 323–340. Available at: *https://www.sciencedirect.com/science/article/pii/S0731708517314838?via%3Dihub.*

[15] K. Parker et al., Medication Burden in CKD–5D: Impact of dialysis modality and setting, Clin Kidney J. 2014, 7: 557–561. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389130/pdf/sfu091.pdf.*

compliance with the guidance for industry on Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.[16] When the Type 9 NDA is submitted, it is given the same NDA Type as the pending NDA. When one application is approved, the other application will be reclassified as a Type 9 NDA regardless of whether it was the first or second NDA actually submitted. After the approval of a Type 9 NDA, FDA will ''administratively close'' the Type 9 NDA and thereafter only accept submissions to the ''parent'' NDA.

We stated that we believed that since Type 9 NDA is a new clinical indication, this suggests that a drug manufacturer is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs, and we consider this to be sufficiently innovative to warrant TDAPA eligibility.

We noted that we believed renal dialysis drugs that are classified as NDA Types 1, 2, and 4 are all innovative and therefore we proposed that these drugs should continue be eligible for the TDAPA. We stated that when the ''parent NDA'' is Type 1, 2, or 4, Type 9 NDA would be a new indication of those innovative drugs. Therefore we expressed that the Type 9 NDA, when the ''parent'' is Type 1, 2, or 4, is just as innovative as Type 1, 2, or 4 and therefore should also be eligible for the TDAPA. We noted that we believed applying the TDAPA with respect to Type 9 NDA new renal dialysis drugs would assist ESRD facilities in adopting these drugs into their treatment protocols for patients, when these drugs are warranted for use in that subset of patients.

(e) Type 10 NDA—New Indication or Claim, Drug To Be Marketed Under Type 10 NDA After Approval

In the CY 2020 ESRD PPS proposed rule (84 FR 38345), we explained that a Type 10 NDA is for a drug product that is a duplicate of a drug product that is the subject of either a pending or approved NDA, and the applicant intends to market the drug product under this separate Type 10 NDA after approval. We further explained that a Type 10 NDA is typically for a drug product that has a new indication or claim, and it may have labeling and/or a proprietary name that is distinct from that of the original NDA. When the Type 10 NDA is submitted, it would be given the same NDA Type as the original NDA unless that NDA is already approved. When one application is approved, the other would be reclassified as Type 10 NDA regardless of whether it was the first or second NDA actually submitted.

We stated that we believed renal dialysis drugs with the Type 10 NDAs are sufficiently innovative and should be eligible for the TDAPA because a new indication for a previously submitted drug that is applicable to renal dialysis advances the field and suggests the drug manufacturer is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs. We noted that we believed this could provide savings in terms of time-to-market and research and development, which could be reflected in the launch price of the drug. We further stated that we believed applying the TDAPA with respect to Type 10 NDA new renal dialysis drugs will assist ESRD facilities in adopting these drugs into their treatment protocols for patients when these drugs are warranted for use in that subset of patients.

(f) FDA Approvals of BLAs Submitted Under Section 351 of the PHS Act

In the CY 2020 ESRD PPS proposed rule (84 FR 38346), we stated that under our proposal, products that are licensed under section 351 of the PHS Act, which occurs for biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, would continue to be eligible for the TDAPA.

We explained that a BLA submitted under section 351(a) of the PHS Act is a ''stand-alone BLA'' that contains all information and data necessary to demonstrate that (among other things) the proposed biological product is safe, pure, and potent.

We explained that an application for licensure of a proposed biosimilar biological product submitted in a BLA under section 351(k) of the PHS Act must contain information demonstrating that the biological product is biosimilar to a reference product. 'Biosimilar' means ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product'' (see section 351(i)(2) of the PHS Act).

We explained that an application for licensure of a proposed interchangeable product submitted in a BLA under section 351(k) of the PHS Act must meet the standards for ''interchangeability.'' To meet the standards for ''interchangeability,'' an applicant must provide sufficient information to demonstrate biosimilarity, and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider (see section 351(i)(3) of the PHS Act). Further information regarding biosimilar biological products is available on the FDA website.[17]

We stated that CMS continues to support the development and the utilization of these products that contain innovative technology for the treatment of ESRD. We explained that the process for licensure of biosimilar biological products is a different pathway than that for generic drugs and has different requirements. We noted that we believed that a categorical exclusion from TDAPA eligibility for all biological products that are biosimilar to or interchangeable with a reference biological product, would disadvantage this sector of biological products in a space where we are trying to support technological innovation. While the products themselves are highly similar to the reference biological product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biosimilar biological product and the biological reference product in terms of the safety, purity, and potency of the product, CMS believes the technology used to develop the products is sufficiently new and innovative to warrant TDAPA payment at this time.

However, we noted that unlike NDAs submitted pursuant to sections 505(b)(1) or 505(b)(2) of the FD&C Act, we did not have a categorical system to use as a proxy for assistance in determining which types of applications would meet

[16] FDA. Guidance for Industry. Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees. Available at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf.*

[17] *https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars.*

the intent of the TDAPA policy. Therefore, we proposed to continue to allow all biological products that are biosimilar to or interchangeable with a reference biological product to remain eligible for the TDAPA instead of proposing to exclude all of them.

In the CY 2020 ESRD PPS proposed rule (84 FR 38346), we noted that we were aware that there are similar concerns about providing the TDAPA for these products that there are with generic drugs. Specifically, we explained that according to a recent report, increased drug class competition for biosimilar biological products has not translated into pricing reductions, and there was a market failure contributing to the rising costs of prescription drugs. The researchers noted that the increases were borne solely by Medicare.[18] We stated that we would continue to monitor future costs of biosimilar biological products as they pertain to renal dialysis, the TDAPA, and the ESRD PPS.

With regard to new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we stated that we believed continuing to include these drugs and biological products as eligible for the TDAPA focuses payment to those products that are innovative in a way that meets the intent of the adjustment. That is, our intention is to support innovation by helping ESRD facilities make appropriate changes in their businesses to adopt such products, provide additional payment for such associated costs, incorporate these drugs and biological products into their beneficiaries' care plans and potentially promote competition among drugs and biological products within the ESRD PPS functional categories. We stated that we planned to continue to monitor the use of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category and will carefully evaluate the products that qualify for the payment adjustment. We noted that for new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the purpose of the TDAPA continues to be a pathway toward a potential base rate modification.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38344), that compared to the TDAPA policy finalized in the CY 2019 ESRD PPS final rule, we believed that these proposed revisions would reduce CY 2020 Medicare expenditures for new renal dialysis drugs and biological products, which would also have a better downstream impact for beneficiary co-insurance. Specifically, we noted that under the expanded policy finalized in the CY 2019 ESRD PPS final rule (83 FR 56932), effective January 1, 2020, the TDAPA would apply for all new renal dialysis drugs and biological products. We stated that we believed that since our proposed policy would carve out certain drug types from being eligible for the TDAPA and would be more limited than the expansive policy finalized in the CY 2019 ESRD PPS final rule for CY 2020, there would be lower Medicare expenditures in CY 2020. Further, the downstream effect of lower Medicare expenditures is lower co-insurance for beneficiaries.

We stated that based on our past experience and our expectation of detailed analysis of future drug product utilization, pricing and payment, we anticipated proposing further refinements to the TDAPA policy through notice and comment rulemaking in the future.

Commenters generally supported our proposal to refine the TDAPA eligibility criteria to target more innovative drugs and biological products. However, they had specific suggestions regarding changes to the proposal. For example, commenters provided suggestions for renal dialysis drugs and biological products that should be excluded (biosimilar biological products), included (first ESRD new indication), and other eligibility criteria (SCI).

The comments and our responses to the comments on our proposal to rely on, as a proxy, the NDA Classification Codes, as well as the proposal for updating the TDAPA exclusions when FDA makes changes to the NDA Classification Codes, are set forth below.

Comment: MedPAC commended CMS for reconsidering the TDAPA eligibility criteria and proposing a standard that is stricter than the one the agency adopted in the CY 2019 ESRD PPS rulemaking. Several commenters supported the use of the TDAPA for encouraging the adoption of new and innovative renal dialysis products by ESRD facilities, and encouraged us to finalize the proposal to exclude drugs for which the NDA Types are for products that are not truly innovative. They recommended that CMS describe when a drug or biological product is considered to be truly innovative. If a product qualifies, it should receive the TDAPA. One drug manufacturer specifically supported CMS's proposal to use NDA Classification Codes to establish TDAPA eligibility, and to maintain eligibility for drugs approved through NDA Types 1, 2, 4, 9, and 10. One national dialysis association noted that the NDA Classification Codes seem to be reasonable proxies for exclusion of products from TDAPA that are technically ''new'' but not necessarily truly innovative. Commenters who supported the use of the NDA Classification Codes recognized that the codes could change and understood we would consider potential revisions to the regulatory language in that case.

However, one drug manufacturer noted that the NDA Classification Codes are contained in an FDA MAPP that is not subject to public notice, input, or comment, and that can be changed at any time by FDA without providing notice to or seeking input from stakeholders or from CMS. The manufacturer noted that the NDA Classification Codes are not codified in any statutory or regulatory provision and were created solely for FDA's administrative purposes, without any relevance to assessments of innovativeness or therapeutic value.

A drug manufacturer did not support CMS' proposal to exclude certain NDA Types from TDAPA eligibility. The company stated the FDA's NDA Classification Codes are a blunt instrument and an inadequate standard on which to judge innovativeness. In addition, the company stated that the proposal pegs the use of NDA Classification Codes to the version dated November 4, 2015 and makes no provision for an updated future version of such codes.

Response: We appreciate the supportive comments regarding our TDAPA proposal and specifically our proposed reliance on the FDA NDA Classification Codes as a proxy. We also appreciate the supportive comments about our proposal to analyze any changes that FDA makes to the NDA Classification Codes when they are publicly available and propose in the next ESRD PPS rulemaking cycle any necessary revisions to the TDAPA exclusions.

Regarding the comments that FDA created the NDA Classification Codes for administrative purposes and they should not be used to assess innovativeness or therapeutic value, and the comment requesting that we describe when a drug or biological product is considered to be truly innovative, we believe FDA's NDA Classification Codes provide an objective basis that we can use to distinguish innovative from noninnovative renal dialysis drugs and

[18] A. San-Juan-Rodriguez et al. ''Assessment of Price Changes of Existing Tumor Necrosis Factor Inhibitors After the Market Entry of Competitors.'' JAMA Intern Med 2019. Feb 18. *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724390.*

biological products. That is, using the NDA Classification Codes will help us in our effort to support innovation by directing Medicare resources to innovative renal dialysis drugs and biological products, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost.

We acknowledge that the NDA Classification Codes are not subject to public notice, input, or comment, and can be changed at any time by FDA without providing notice to or seeking input from stakeholders or from CMS. As discussed in section II.B.1.b of the CY 2020 ESRD PPS proposed rule, the Classification Codes assigned to an NDA generally describe FDA's classification of the relationship of the drug to drugs already marketed or approved in the U.S. As we discussed in the CY 2020 ESRD PPS proposed rule, if FDA makes changes to the NDA Classification Codes in FDA/CDER MAPP 5018.2, we would assess FDA changes at the time they are publicly available and we would analyze those changes with regard to their implications for the TDAPA policy under the ESRD PPS. We would plan to propose any necessary language revisions to the exclusions set forth in proposed § 413.234(e) in the next rulemaking cycle.

Comment: Many commenters appreciated CMS addressing the concerns raised by stakeholders regarding the all-inclusive approach to TDAPA eligibility finalized in the CY 2019 ESRD PPS final rule. They stated we should finalize the use of the FDA NDA Classification Codes as proposed, with one modification. Specifically, if a product falls into an excluded NDA Type, but obtains FDA approval for its first ESRD new indication, regardless of its NDA designation, that product should be eligible for TDAPA. These commenters stated that without such modification, using the NDA Classification Codes has the significant potential to exclude from TDAPA eligibility truly new and innovative drugs for ESRD patients.

Some commenters noted that CMS recognizes in its discussion of the Type 10 NDA that a new ESRD indication for a previously approved non-ESRD drug advances the field and presents a new approach to provide care for ESRD patients. The commenters stated that not all products for which a manufacturer obtains a new ESRD indication will be approved through a Type 10 NDA. For example, a product originally approved for a non-ESRD indication through an excluded NDA Type, may have a first ESRD new indication added through an NDA supplement to that NDA, thus resulting in the new ESRD product being excluded from TDAPA eligibility. The commenters asserted that the innovation and investment by this manufacturer to obtain the first ESRD new indication is no less than that of the manufacturer who submits a Type 10 NDA for a new indication, but CMS's proposed criteria would exclude such a drug from TDAPA eligibility. The commenters stated that, by definition, a first ESRD new indication denotes that the product has not been approved for this population previously and is consistent with CMS's intent to limit the TDAPA to truly innovative products.

An ESRD facility and a national dialysis association expressed concerns regarding CMS's proposal to exclude FDA NDA Type 5 and Type 7 from TDAPA eligibility. Regarding Type 5, they believe that new drug formulations may offer specific benefits to patients. For example, they stated that if phosphate binders currently marketed in tablet form were to become available in a topical form, it might offer benefits like decreased satiety and decreased pill burden, which could lead to improved compliance with the medications and increased protein intake, which has been associated with better outcomes for patients with ESRD treated by maintenance dialysis. Regarding Type 7, commenters agreed with CMS that if a drug is being used by an ESRD facility, there is no need for additional payment in the form of TDAPA. However, they believe there should be a requirement to verify that use before CMS concludes that the drug is not eligible.

A few commenters noted that the proposed exclusions would remove from TDAPA eligibility important therapeutic advances that may happen to be new formulations, new indications, and new dosage forms, which can make it easier for the patient to adhere to prescribed therapy and offer significant value in increased quality of life. Commenters noted that the proposal would exclude, for example, a drug that receives a new ESRD indication or is a reformulation that results in a patient needing only one, rather than several doses a day, requiring the patient to be awoken multiple times during the night. They stated that to exclude such new drugs and biological products from TDAPA eligibility could erect barriers to patient use and chill new research into the entire category of ESRD medicine, and would be a great disservice to patients, providers, and the Medicare program, as it would inhibit the ability of physicians and ESRD facilities to incorporate these innovative new therapies into the care of and treatment protocols for their patients with ESRD. In contrast, one non-profit provider association expressed support for CMS's proposal to exclude line extensions from TDAPA eligibility.

One drug manufacturer stated the proposed approach imposes a framework that would categorically exclude many types of innovative new drugs from TDAPA eligibility. For example, the manufacturer stated that a new drug potentially may be assigned a Type 3 or Type 5 NDA by FDA, even if FDA reviews and approves the product under an original NDA through the 505(b)(1) pathway, and even if the drug reflects innovative characteristics and facilitates important benefits, such as improving patient outcomes through safety or efficacy advantages, reducing harmful complications, or providing patients (including specific subpopulations of patients) with new treatment options and/or new access options. The drug manufacturer stated that our proposed approach would impair providers' ability to evaluate and incorporate these important types of innovative new medicines into their practice, and would have detrimental access implications for patients. As such, it would undermine the goals that CMS seeks to achieve through TDAPA with respect to facilitating innovation, competition, and the ability of ESRD facilities to test and accommodate new therapies in their care plans. The drug manufacturer strongly encouraged CMS to modify the proposed criteria to allow for TDAPA eligibility for Type 3 and Type 5 NDAs, noting that new dosage forms and new formulations (among other differences), particularly for IV and injectable products, reflect significant innovation and lead to new access options and treatment flexibility for patients.

One drug manufacturer urged CMS to adopt the modification that a Type 5 drug should be eligible for TDAPA if it contains a previously approved active moiety and obtains approval for an ESRD-related indication for which the active moiety was not previously approved. The drug manufacturer asserted that, to achieve a new indication, a manufacturer will be required to invest the same resources and perform the same research and development, whether the new indication is approved through a Type 10 NDA or a different pathway, such as a supplement to the original NDA.

The commenter noted that there are a myriad of considerations that go into any particular drug's FDA approval

pathway. Because the reasoning to include ''Type 5'' for a new indication is similar to that for including Type 10 NDA, the commenter strongly urged CMS to also include Type 5 new indication. The commenter stated that providing TDAPA eligibility when a drug containing a previously approved active moiety is approved for an ESRD indication for which such active moiety was not previously approved—regardless of NDA type—would also encourage manufacturers to pursue development strategies that capitalize on the benefits of expanding uses for current treatments into new indications in the ESRD space. The drug manufacturer urged CMS to recognize that a previously approved drug product that later becomes approved for an ESRD indication should be eligible for TDAPA.

Response: We thank commenters for the helpful comments and suggestions. With regard to the suggestions that we allow new renal dialysis drugs and biological products that have a new indication for ''ESRD'' or ''ESRD-related'' conditions to be eligible for the TDAPA, we understand this to mean that the drug was not previously indicated for a condition or conditions associated with ESRD, but after clinical trials, the drug has been proven to be safe and efficacious for the treatment or management of a condition or conditions associated with ESRD, and the drug falls within an ESRD PPS functional category.

At this time, we do not believe that making a first ESRD new indication for a Type 5 NDA drug eligible for the TDAPA is consistent with CMS's intent to limit the TDAPA to truly innovative products. We believe that while Type 5 NDA drugs may have clinical benefits to patients over previously approved products, we did not make that assessment as part of ESRD PPS payment policy because these are drugs that are currently on the market but may have been reformulated or may be line-extensions. We do not believe that the characteristics of Type 5 NDA drugs would advance the intent of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category. As we stated in section II.B.1.c.i.(b) of the CY 2020 ESRD PPS proposed rule (84 FR 38342), we do not believe that the types of changes represented by Type 5 NDAs enhance our goal of increased competition with the overarching goal of lowering drug prices. To the contrary, it seems that a goal of line extensions can be to thwart competition. Studies indicate that there is no lowering of prices through competition from line extensions. Rather, it has been reported that prices remain rigid and are not lowered. In fact, not only can product line extensions thwart competition, but they inherit the market success of the original brand, sometimes with little quality improvement over the original brand. We believe making Type 5 NDA drugs eligible for the TDAPA, even for the first ESRD new indication, may cause more attention to be diverted to the less costly duplication of drugs that are already available rather than those that may be more expensive to develop and bring to market. In addition, this could cause an influx of non-innovative drugs to the dialysis space, potentially crowding out innovative drugs. For these reasons, we continue to believe that providing the TDAPA to ESRD facilities to support the uptake of a drug reflected in an ESRD PPS functional category that may be a line extension or reformulation in their business model is not a judicious use of Medicare resources.

In response to the commenter suggesting that Type 5 NDA drug products are the same as Type 10 NDA drug products, we believe that they are distinct in that Type 5 NDAs are reformulations or line extensions that are not truly innovative and Type 10 NDA drug products are not. As we discussed in the CY 2020 ESRD PPS proposed rule in section II.B.1.c.ii.(e) (84 FR 38345), we believed that Type 10 NDA drug products are sufficiently innovative because a new indication for a previously submitted drug that is applicable to renal dialysis advances the field and suggests the drug manufacturer is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs. We noted that we believed this could provide savings in terms of time-to-market and research and development, which could be reflected in the launch price of the drug. We further stated that we believed applying the TDAPA with respect to Type 10 NDA new renal dialysis drugs will assist ESRD facilities in adopting these drugs into their treatment protocols for patients when these drugs are warranted for use in that subset of patients.

In addition, as we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38340), we believe FDA's NDA Classification Codes provide an objective basis that we can use to distinguish innovative from noninnovative renal dialysis service drugs. We believe that distinguishing drugs in this categorical manner helps us in our effort to support innovation by directing Medicare resources to renal dialysis drugs and biological products that are not reformulations or new dosage forms, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost. We also believe that including some characteristics of an NDA Type without including others undermines the objective basis of the use of this system as a proxy to determine if a new renal dialysis drug or biological product is innovative for the purposes of the TDAPA.

The NDA Classification Code Type 7 is a drug that has been previously marketed but without an approved NDA. With regard to the suggestion that we verify ESRD facility use of a Type 7 drug before deciding that the drug is ineligible for the TDAPA, we do not believe the characteristics of Type 7 would advance the intent of the TDAPA policy because these drugs are already on the market and may already be in use in the ESRD facilities. Thus, providing the TDAPA for Type 7 NDA drugs would not assist the facilities in their uptake for their business model.

With regard to the comment about a drug currently marketed in tablet form that becomes available in a topical form, we believe the commenter is actually referring to Type 3 NDA, which is an NDA Classification Code that we are excluding from the TDAPA. Regarding the comments about excluding line extensions such as new formulations (Type 5) and new dosage forms (Type 3), we do not believe these drugs are sufficiently innovative to warrant TDAPA eligibility and we do not want to provide perverse incentives for ESRD facilities to choose a new dosage form in order to obtain the TDAPA. Although these drugs may provide an expansion of patient treatment options, we continue to believe that these changes are not innovative and should not be eligible for the TDAPA for new renal dialysis drugs and biological products in existing functional categories.

Regarding the comments about erecting barriers to patient use, chilling new research into ESRD medicine, and inhibiting the ability of physicians and ESRD facilities to incorporate these innovative new therapies into treatment protocols for their ESRD patients, we note that beneficiaries have access to all FDA-approved drugs and biological products for renal dialysis services, regardless of whether the ESRD facility receives TDAPA or not. The TDAPA eligibility does not prevent patient access to any renal dialysis services. ESRD patients currently have, and will

continue to have access to all FDA-approved renal dialysis drugs and biological products. Our policy would not prevent a physician from determining that the new Type 3 drug facilitates additional benefits. Such benefits could include improving patient outcomes through safety or efficacy advantages, reducing harmful complications, or providing patients with new treatment options over and above what is currently available. Then, the physician could include the drug in a patient's plan of care for the ESRD facility to furnish to that patient. We note that because Type 3 drugs would not eligible for the TDAPA, there would be no additional co-insurance for the beneficiary. We continue to believe that the TDAPA for renal dialysis drugs and biological products that fall within an ESRD PPS functional category should be applied only to truly innovative drugs and biological products. We thank and agree with the non-profit provider association that expressed support for our proposal to exclude line extensions from TDAPA eligibility.

After careful consideration of the comments, we are finalizing our proposal to exclude certain NDA types from TDAPA eligibility. That is, we are finalizing to exclude Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8.

Comment: A physician association expressed support for the proposal to revise the TDAPA eligibility criteria but stated it is critical for CMS to support and specifically focus on innovations that also pertain to the pediatric space. The association noted that new products and therapies that come to market are not always tested in the pediatric population, and policies must be put in place to change this moving forward. The association emphasized that children and adolescents are not simply ''little adults.'' Rather, they have a unique physiology characterized by maturing organ function, body metabolism, and body distribution characteristics distinct from what adults manifest. Due to these differences, the association noted, the safety and efficacy data developed for adults and only studied in adults may not be appropriate for pediatric patients. The association recognized that the small number of pediatric patients complicates conducting safety, efficacy, or interventional trials in children, but noted this data is crucial to allow children to also benefit from innovation.

Response: We thank the physician association for its support for the refinement of TDAPA eligibility and for its comments regarding the pediatric dialysis population. We recognize that the pediatric dialysis population has unique needs and that those needs must be closely examined. Our data analysis contractor will be holding a Technical Expert Panel meeting in December 2019 and intends to facilitate discussions on the topic of pediatric dialysis.

Comment: Some commenters strongly encouraged CMS and FDA to work together to: (i) Provide greater transparency into the NDA Type decision; and (ii) develop a process for manufacturer involvement in that decision. A commenter also suggested that a formal process be adopted to request and appeal NDA Type classification decisions.

Response: We have been conferring with FDA regarding new and innovative renal dialysis products, and intend continue to work with FDA in the future to discuss NDA Types as they pertain to new renal dialysis drugs and biological products. It is our understanding that FDA will meet with drug manufacturers for discussions regarding the NDA Types that may be considered for their applications.

Comment: MedPAC, a professional association and 2 pharmaceutical companies commented that they disagreed with and did not support the proposal to use the NDA Classification Codes to determine TDAPA eligibility for new renal dialysis drugs, arguing that this is not an appropriate or well-suited proxy for determining TDAPA eligibility. They stated that they did not support CMS's proposed approach to judge the innovativeness of drugs. MedPAC commented that an SCI standard would be the best way to ensure taxpayer and beneficiary dollars are spent to improve patient care or outcomes. MedPAC noted that using a clinical improvement standard for the TDAPA policy would be consistent with: (1) Medicare's payment for certain new technologies under the outpatient PPS (OPPS) and inpatient PPS (IPPS); and (2) CMS's proposal to apply the IPPS SCI standard (specified in § 412.87(b)(1)) to the add-on payment for new ESRD equipment and supplies.

MedPAC asserted that to protect the well-being of beneficiaries and ensure good value for the Medicare program and taxpayers, Medicare should not pay more for drug or biological products that have not yet been proven to provide better outcomes for beneficiaries. Therefore, MedPAC noted, a new drug or biological product should not qualify for the TDAPA if there is no evidence that it is an improvement relative to existing care. Similarly, a large dialysis organization (LDO) requested a patient-centered approach to TDAPA eligibility with clear evidence of an improvement in one or more patient-centered outcomes. The LDO suggested that CMS could structure a TDAPA clinical improvement standard similar to the standard that the agency uses to pay for new technologies under the IPPS (specified in § 412.87(b)(1)).

MedPAC stated that CMS's approach relies on FDA approval pathways using a standard that is less stringent than a clinical improvement standard for all drugs and biological products that fit into an ESRD functional category, and should not be used, because on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries. The Commission also asserted that the Medicare program, not FDA, should adjudicate spending determinations based on the specific needs of the Medicare population. MedPAC stated that the evaluation of the evidence of whether a new drug or biological product improves Medicare beneficiaries' outcomes should rest with CMS. One non-profit provider association and an LDO suggested the proposed policy could go further by also addressing whether new drugs for renal care represent an SCI, and that the proposed policy stands in contrast to the more robust policy that CMS proposed for new equipment and supplies based on the Medicare IPPS new technology add-on payment. These commenters stated that while it is expected that some drugs with a new molecular entity or new active ingredient will represent an SCI, not all will. They urged CMS to also consider whether a new drug or biological product addresses the needs of a patient population unresponsive to, or ineligible for, currently available treatments, or significantly improves clinical outcomes for a patient population compared to currently available treatments. They maintained that CMS' TDAPA policy should spur innovation by targeting products that do more than offer minor, if any, clinical improvement. For example, a drug that significantly improves compliance because it is not accompanied by complications such as gastrointestinal effects, which can deter patient compliance, might warrant eligibility for TDAPA and higher payment. The commenters suggested that CMS should consider refining TDAPA eligibility based on its own assessment of a product's clinical significance, similar to its proposed approach for the TPNIES.

One drug manufacturer commented that relying on NDA Classification Codes for TDAPA eligibility would significantly discourage investment in the ESRD space. The manufacturer argued that the proposed changes would create a rigid and narrow set of criteria for TDAPA eligibility that would significantly limit the chances for new products to qualify for the opportunity to be evaluated and incorporated into ESRD care plans. The manufacturer expressed concern that innovators will be discouraged from investing time and resources in ESRD research, development, and innovation, because product uptake potential will be uncertain and unlikely. That, in turn, would also result in reduced competition, to the further detriment of ESRD stakeholders and the Medicare program, according to the commenter.

Response: We appreciate the thoughtful and insightful comments from MedPAC and other commenters. With regard to MedPAC not supporting our proposed approach to judge the innovativeness of drugs, and noting that an SCI standard is the best way to ensure taxpayer and beneficiary dollars are spent to improve patient care or outcomes, we respectfully disagree.

We believe that using the NDA Classification Codes will help us to objectively distinguish drugs that would assist our efforts to support innovation by directing Medicare resources to those new renal dialysis drugs and biological products. We also believe that our proposed approach would promote our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost. Additionally, our proposed approach would promote our goal of providing a transition period for the unique circumstances experienced by ESRD facilities and to allow uptake of the new product. That is, our intention is to support innovation by helping ESRD facilities make appropriate changes in their businesses to adopt such products, provide additional payment for such associated costs, incorporate these drugs and biological products into their beneficiaries' care plans and potentially promote competition among drugs and biological products within the ESRD PPS functional categories. We proposed to narrow the types of new renal dialysis drugs and biological products within the ESRD PPS functional groups that are eligible for TDAPA, effective January 1, 2020. To do so, we proposed to extend TDAPA eligibility to those renal dialysis products that are new and innovative, not just new, based on the FDA's NDA Classification Code used for investigational product review. As detailed in the CY 2020 ESRD PPS proposed rule, we believe that the NDA classifications that we are excluding, which includes Type 3 (new dosage forms) are not innovative.

With regard to having an SCI standard, as we discuss in section II.B.1.c of this final rule, we continue to believe that unlike many Medicare beneficiaries, the Medicare ESRD beneficiary is significantly complex, with each patient having a unique and challenging profile, due to a variety of causes, including biochemical differences, genetics and/or co-morbidities, all of which factor into the medical management of drugs and biological products. Practitioners should have the opportunity to evaluate the appropriate use of a new drug or biological product and its effect on patient outcomes and interactions with other medications the patient is currently taking, with other co-morbidities, and with what is age-appropriate. Further, unlike the SCI criteria for the TPNIES, where biochemical differences in patients rarely have an impact, the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic predisposition and comorbidities. Each patient's unique medical profile must be assessed by the patient's physician in determining the plan of care, and we believe that, rather than being too rigid and limiting investment in new therapies, using the NDA Classification Codes for purposes of determining TDAPA eligibility will help promote innovative therapies for the ESRD patient on dialysis and support ESRD facility uptake.

Comment: One drug manufacturer stated CMS should be cautious in taking any steps to judge the innovativeness of new renal dialysis drugs. Beyond the specific proposals to narrow the TDAPA eligibility, the company questioned whether CMS should be judging which drugs are or are not innovative. The company acknowledged CMS' desire to provide an objective basis to distinguish innovative from non-innovative renal dialysis service drugs, but asserted that it could be outside our authority to judge innovativeness of new drugs, regardless of the standard employed. Such a step could contravene section 1801 of the Act, which prohibits the Medicare program from interfering in the practice of medicine. The commenter states that the choice of prescribing any drug, including a new ESRD drug, should be between a patient and his or her doctor. As an example, they noted the Part D program has exhibited continuously high beneficiary satisfaction and costs below estimates, but has explicit prohibitions on government involvement in setting any kind of formulary.

Response: We appreciate this comment and believe that in using the FDA NDA Classification Codes, we are not interfering in the practice of medicine. We are not dictating what drugs may or may not be used on what patients. Rather, all FDA-approved renal dialysis drugs and biological products are accessible to all ESRD patients for the treatment of ESRD. As noted previously, we believe FDA's NDA Classification Codes would provide an objective basis that we can use to distinguish innovative from noninnovative renal dialysis service drugs for eligibility for the TDAPA for renal dialysis drugs that are included in functional categories. Unlike Part D, we are not setting a formulary, and we do not prohibit accessibility of any FDA-approved drug that is indicated for an ESRD patient for renal dialysis services. What we are limiting is eligibility for the TDAPA for new renal dialysis drugs and biological products in existing ESRD PPS functional categories to truly innovative products. We continue to believe that practitioners and their patients should make treatment decisions collaboratively.

Comment: We received comments from 2 pharmaceutical companies and a few individuals regarding the exclusion of specific products from TDAPA eligibility and the more restrictive eligibility of new renal dialysis drugs and biological products in the CY 2020 ESRD PPS proposed rule from what was finalized in the CY 2019 ESRD PPS final rule, which included all new renal dialysis drugs and biological products. A professional association, a drug manufacturer, a physician and an individual commenter urged CMS not to finalize the proposed changes to the TDAPA eligibility criteria under the CY 2020 ESRD PPS proposed rule, and to instead maintain the CY 2019 ESRD PPS final rule's expanded eligibility criteria for TDAPA, with an effective date of January 1, 2020. They stated that under our current proposal the TDAPA eligibility criteria would be too narrowed, resulting in ESRD facilities not having the opportunity to incorporate the many new and innovative drugs into their care plans and to make appropriate changes in their businesses to adopt such products.

They also commented that, compared to the TDAPA eligibility criteria finalized under the CY 2019 ESRD PPS

final rule, the CY 2020 ESRD proposed rule has significant differences that affect what the stakeholders have been expecting, planning, relying upon and preparing for since the November 2018 publication of the CY 2019 ESRD PPS final rule. The commenter noted that those provisions currently are scheduled to take effect on January 1, 2020 and asserted that changing the TDAPA eligibility criteria would provide stakeholders with very little time between issuance of a final rule and the proposed effective date to plan for or adapt to any changes. The commenters stated that implementing such a significant change so quickly would be imprudent and unfair to ESRD stakeholders.

One drug manufacturer commented that NDA approval pathways, rather than NDA Classification Codes, are the clearest method for making TDAPA eligibility determinations for new renal dialysis drugs. The same drug manufacturer noted that for drug products, approval through FDA's statutory 505(b)(1) NDA pathway reflects a rigorous process used for new and novel drugs, and requires substantial clinical data and robust review. As such, drugs approved under the 505(b)(1) NDA pathway should be eligible for TDAPA. The drug manufacturer opined that this is a clear standard anchored in statute and not subject to changes based in internal FDA policies and procedures created for administrative purposes.

In addition, the drug manufacturer noted that eligibility on the basis of NDA approval pathway allows clarity for stakeholders and reflects an appropriate balance between the goals CMS has articulated in the CY 2020 ESRD PPS proposed rule with respect to incentives for innovation and concerns regarding costs. The drug manufacturer suggested that CMS should maintain the TDAPA eligibility criteria finalized under the CY 2019 ESRD PPS final rule, which would apply the TDAPA to all new renal dialysis drugs or biological products approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the PHS Act, effective January 1, 2020. The drug manufacturer explained that basing the TDAPA eligibility criteria on NDA approval pathway also would be consistent with CMS regulations and policies in other contexts that refer to NDA approval pathways. For example, the Medicaid program has definitions for innovator drugs that focus on NDA approval pathways, and the CMS HCPCS Level II coding process involves considerations of FDA approval pathways (as well as certain FDA Orange Book designations), among other criteria. The commenter further noted that, if CMS does move forward with the proposed modifications, the changes should not go into effect until January 1, 2021. The commenter urged CMS to re-evaluate and revise both the substance of the proposed TDAPA eligibility changes, as well as the proposed effective date for any changes that may be finalized.

Response: Thank you for these comments. As discussed in the CY 2020 ESRD PPS proposed rule, we re-evaluated the expanded TDAPA policy in the CY 2019 ESRD PPS final rule based on numerous calls, correspondence, meetings and comments, requesting we narrow TDAPA eligibility, as well as based on our overall policy goals for the TDAPA and the financial impact of those broad-reaching goals. As the TDAPA eligibility policy finalized in the CY 2019 ESRD PPS final rule had not been implemented yet, and as we evaluated our goal to support innovation and promote competition, while simultaneously being prudent with regard to Medicare spending, we weighed all aspects of the current and future risks in these areas and carefully made a decision to propose to narrow the CY 2019 ESRD PPS TDAPA eligibility policy in the most objective way possible. As noted previously, we are finalizing this proposal effective January 1, 2020. We do not believe postponing the implementation of this new policy to January 1, 2021 is necessary and we believe doing so would be operationally challenging.

With regard to using the FDA approval pathways to determine innovation, we found the use of only the 505(b)(1) pathway to be too narrow and the 505(b)(2) pathway to be too broad. The commenter mentioned using Medicaid's definition of innovator drugs, but that definition includes line extensions and generic drugs and we do not believe those drugs and biological products to be truly innovative for purposes of our TDAPA policy.

Comment: One commenter requested that CMS review every new FDA approved drug for dialysis.

Response: To date, only one type of renal dialysis drug (calcimimetics) has been eligible for the TDAPA. We anticipate that additional renal dialysis drugs and biological products will become eligible in the future and are exploring the potential use of application forms requesting specific information. Consistent with our current policy, we will review all requests submitted for the TDAPA.

We do not agree with the commenter that we should review every new FDA approved drug for dialysis. We believe that it is appropriate for us to use the process that we discussed in the CY 2016 ESRD PPS final rule and on the CMS website [19] whereby after FDA approves drugs and biological products for use in ESRD patients, the products then go through a process to establish a billing code, that is, the HCPCS code process. When the HCPCS application is submitted and the drug manufacturer notifies us of its interest in eligibility for the TDAPA we then analyze the information in the FDA-approved labeling and the HCPCS application information, including studies submitted as part of these two standardized processes. This process provides an approach that facilitates a dialogue between the interested stakeholder and CMS creating a more robust forum for the evaluation of the eligibility for the drug or biological product for the TDAPA under the ESRD PPS.

Comment: One national dialysis association stated that CMS should remain open to future refinements of the TDAPA eligibility requirements, including the ability to make exceptions to these rules if a drug would be of significant clinical value for the treatment of ESRD. They asserted that the excluded NDA Classification Codes are a good place to start, but CMS should ensure that this policy is adjusted or that exceptions are granted, as needed.

Response: We appreciate the support and noted in our CY 2020 ESRD PPS proposed rule (84 FR 38346) that we would remain open to future refinements of the TDAPA eligibility requirements. Specifically, we said that based on our past experience and our expectation of detailed analysis of future drug product utilization, pricing and payment, CMS anticipates proposing further refinements to the TDAPA policy through notice and comment rulemaking in the future.

We received several comments from stakeholders specifically supporting the exclusion of generic drugs. The comments and our responses to the comments on our proposal to exclude generic drugs are set forth below.

Comment: Some commenters supported our proposal to exclude drugs approved by FDA under section 505(j) of the FD&C and drugs for which the NDA types are for products that are not truly innovative. MedPAC and several

[19] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.*

other commenters supported the exclusion of generic drugs from TDAPA eligibility. However, they also stated CMS should exclude biosimilar biological products because they would be neither new nor innovative. MedPAC questioned our proposal that products that receive FDA approval under section 351 of the PHS Act, which occurs for new biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, would continue to be eligible for the TDAPA, even though we acknowledged that these products may not be innovative. MedPAC asserted that CMS should not pay more for a new technology without evidence that it improves outcomes for Medicare beneficiaries. One non-profit provider association recommended CMS revisit its assumptions and conclusions about biosimilar biological products in future rulemaking with the benefit of more experience.

Response: We thank commenters for the support regarding the exclusion of generic drugs reflected in ESRD PPS functional categories from eligibility for the TDAPA. CMS continues to support the development and the utilization of these products that contain innovative technology for the treatment of ESRD. As we discussed in the CY 2020 ESRD PPS proposed rule, the approval process for biosimilar biological products is a different pathway than that for generic drugs and has different requirements. We believe that a categorical exclusion from TDAPA eligibility for all biological products that are biosimilar to or interchangeable with a reference biological product, would disadvantage this sector of biological products in a space where we are trying to support technological innovation. While the products themselves may not be innovative, CMS believes the technology used to develop the products is sufficiently new and innovative to warrant TDAPA payment at this time. However, unlike NDAs submitted pursuant to sections 505(b)(1) or 505(b)(2) of the FD&C Act, we do not have a categorical system to use as a proxy for assistance in determining which types of applications would meet the intent of the TDAPA policy. Therefore, we are finalizing our proposal to continue to allow all biosimilar to or interchangeable with a reference biological products to remain eligible for the TDAPA instead of proposing to exclude all of them.

However, as noted in the CY 2020 ESRD PPS proposed rule, we are aware that there are similar concerns about providing the TDAPA for these products that there are with generics, that increased drug class competition for biosimilar biological products did not translate into pricing reductions, and there was a market failure contributing to the rising costs of prescription drugs with the increases borne solely by Medicare. Therefore, we will monitor future costs of biosimilar biological products as they pertain to renal dialysis, the TDAPA, and the ESRD PPS, and we may revisit the recommendation to exclude biosimilar biological products from TDAPA eligibility in future rulemaking.

Comment: A few commenters asked about TDAPA eligibility for specific products and their placement in the ESRD PPS functional categories, and requested that CMS permit eligibility for the TDAPA for drugs within functional categories with a different mechanism of action. One commenter requested that CMS support FDA Breakthrough Therapy Designation products.

Response: Currently, we have established a TDAPA request process which is available on the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html*. We anticipate establishing a more formal application process in the future as more new renal dialysis drugs and biological products become available. With regard to TDAPA eligibility for specific products, we would need to review the submitted TDAPA request to make that determination. We intend to provide further information regarding a TDAPA application process in the future.

Regarding the comment about FDA Breakthrough Therapy Designation products, this refers to a drug that is intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition and has preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is granted Breakthrough Therapy Designation by FDA, FDA will expedite the development and review of such a drug. The FDA does not announce when a drug has been granted Breakthrough Therapy Designation. It does not disclose information regarding sponsors who submitted requests for or who have been granted or denied Breakthrough Therapy Designation. Breakthrough Therapy Designation requests are typically submitted to an Investigational New Drug (IND), and the FDA cannot disclose the existence of an IND, or any submissions that have been submitted to the IND, unless it has previously been publicly disclosed or acknowledged per 21 CFR 312.130(a). The restrictions discussed previously create an issue for determining TDAPA eligibility since this information is not publicly available. To the extent a new renal dialysis drug or biological product is designated as a Breakthrough Therapy and otherwise meets the eligibility criteria for the TDAPA, it would be eligible for the add-on payment adjustment.

Comment: Numerous stakeholders requested that CMS increase the ESRD PPS base rate following any one of the following scenarios: At the end of the TDAPA eligibility period; when a new drug is added to the ESRD PPS functional category; or, when a new product emerges within a functional category or composite rate that is of high clinical value to patients and is utilized by a significant number of beneficiaries with ESRD where there are simply not sufficient funds allocated within the ESRD PPS to cover the cost of the new drug. Counter to this, MedPAC asserted CMS should not make duplicative payments for a new product assigned to a functional category by providing the TDAPA for 2 years in addition to paying for its functional category under the ESRD PPS base rate. For example, MedPAC stated, the agency could reduce the TDAPA amount to reflect the amount already included in the ESRD PPS base rate. MedPAC noted that CMS should consider paying a reduced percentage of the estimated incremental cost of the new drug as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices. MedPAC pointed out that CMS proposed a similar approach for the TPNIES. Some commenters suggested that CMS should apply funds not expended under the narrower TDAPA eligibility policy to make ESRD PPS adjustments when it adds new products to the ESRD PPS base rate. These commenters recommended that CMS establish a payment adjustment that equals the incremental difference between any amounts associated with the functional category currently in the base rate attributable to the new product's cost, which may result in CMS adding the product's full cost if the ESRD PPS base rate does not include any such reimbursement or a lesser amount that reflects current dollars in the ESRD PPS base rate.

Another commenter advocated that CMS create a non-budget neutral methodology to incorporate novel or improved technologies, including drugs and devices that will better the lives of

patients with kidney failure, into the ESRD PPS bundled payment and that future novel products or technologies for treating patients with kidney failure will require different reimbursement pathways than the PPS. This commenter stated there needs to be new money for innovative drugs and devices, and that a bundled payment works for drugs, devices, and care strategies that are used by the vast majority of patients at similar doses or that are inexpensive enough to be affordable within a highly capitated payment model. However, the commenter does not believe that a bundled payment works for drugs, devices, and care strategies that are both expensive and used by a minority of patients treated within the capitated payment model, particularly when the total number of patients within each payment unit are sufficiently small that one or 2 high utilizers will make a marked difference in margins.

Response: We appreciate the comments and suggestions of MedPAC and the many commenters regarding increasing the base rate in several scenarios, including making any additions to it in a non-budget neutral manner; reconciling the TDAPA with either what is already in the ESRD PPS base rate or with what is in each ESRD PPS functional category; making separate, non-PPS reimbursement pathways for new and innovative drugs, and fund-shifting from ''would have been'' expenditures under the TDAPA eligibility criteria finalized in the CY 2019 ESRD PPS final rule to adding those dollars to the base rate. As described previously, the comments ranged widely from adding the cost of all new renal dialysis drugs to the ESRD PPS base rate to only adding the difference to what is currently in the base rate, to still more fiscally conservative suggestions of netting out TDAPA expenditures with what is already in the base rate.

As we stated in the CY 2016 ESRD PPS final rule (80 FR 69016), we believe we have the authority to add new renal dialysis services to the bundle under both sections 1881(b)(14)(B) of the Act and 217(c)(2) of PAMA. First, we read section 1881(b)(14)(B)(iii) of the Act as requiring the inclusion of a specific category of drugs in the bundle—that is, drugs and biologicals, including those with only an oral form, furnished to individuals for the treatment of ESRD and for which separate payment was made prior to January 1, 2011. We also read section 1881(b)(14)(B)(iv) of the Act as specifying a different category of items that must be included in the bundle—that is, items and services, which includes drugs and biologicals, not specified by sections 1881(b)(14)(B)(i), (ii), or (iii) of the Act. Second, we read the language of section 217(c)(2) of PAMA—''the Secretary of Health and Human Services . . . shall establish a process for . . . including new injectable and intravenous products into the bundled payment system''— to require us to both define and implement a drug designation process for including new injectable and IV products into the ESRD PPS bundled payment.

As we stated in the CY 2019 ESRD PPS final rule (84 FR 56935), we do not believe it would be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories and that doing so would be in conflict with the fundamental principles of a PPS. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's cost, which creates an incentive for cost control. It is not the intent of a PPS to add dollars to the base rate whenever something new is made available. Additionally, the statute does not require that we add dollars to the ESRD PPS base rate when a new item is available. As we explained in that rule, the intent of the TDAPA for new renal dialysis drugs and biological products that fall within an ESRD PPS functional category is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new drug.

Through the legal levers available to us, we strive to not only support innovation and competition for new renal dialysis drugs and biological products that fall within an ESRD PPS functional category, but also to align resource use with payment, while simultaneously balancing that payment with prudent spending of Medicare dollars. Medicare spending on prescription drugs continues to grow at rates far in excess of inflation, which poses challenges for both CMS and for providers seeking to give patients innovative therapies that can improve health outcomes and quality of life but at a cost that both patients and providers can afford.

Comment: One LDO requested that the drug designation process be patient centered and not increase patient expense for a new drug eligible for the TDAPA in which there is no clear evidence of an improvement in one or more patient-centered outcomes. The LDO stated that improvements in surrogate outcomes, such as laboratory values, is not sufficient. The LDO noted that if a new drug really improves patient-centered outcomes, the ESRD PPS base rate should be increased to pay for it after the 2 year TDAPA period regardless of whether the drug fits into a functional category. However, one national dialysis association referenced CMS' assertion that restricting TDAPA eligibility would reduce CY 2020 Medicare expenditures, which would have a favorable downstream impact on beneficiary co-insurance, and argued that patients are willing to accept higher cost sharing in exchange for any innovation in the ESRD space.

Response: We agree with the LDO that all treatment should be patient-centered, and encourage drug choices be made in discussion with the patient regarding potential improved outcomes weighed against additional out-of-pocket cost to the patient. We note that physicians are not obligated to prescribe a new drug for a dialysis patient if they do not feel it would yield improved clinical outcomes for the additional co-insurance obligation of the patient. For any new renal dialysis drug or biological product that meets the TDAPA eligibility criteria, the 20 percent co-insurance for those drugs is statutorily mandated on the ESRD PPS payment amount, which includes the amount for the TDAPA.

Final Rule Action: After consideration of public comments, for CY 2020, we are finalizing the revisions to the drug designation process regulation as proposed. That is, we are finalizing the proposed revisions to § 413.234 by revising paragraph (b)(1)(ii) and adding paragraph (e), effective January 1, 2020, to specify that a new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the TDAPA if it is a generic drug or if the NDA for the drug is classified by FDA as a certain type—specifically, if the drug is approved under section 505(j) of the FD&C Act or the NDA for the drug is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8.

We also proposed a technical change to § 413.234(a) to revise the definitions ''ESRD PPS functional category'' and ''Oral-only drug'' to be consistent with FDA nomenclature. We proposed to change the definition of ''ESRD PPS functional category'' to replace ''biologicals'' with ''biological products.'' We also proposed to change the definition of ''Oral-only drug'' to

replace ''biological'' with ''biological product.''

We did not receive any comments on our proposed technical changes to § 413.234(a) to revise the definitions. We are therefore finalizing these changes as proposed.

d. Modification of the Basis of Payment for the TDAPA for Calcimimetics in CY 2020

In the CY 2016 ESRD PPS final rule (80 FR 69025 through 69026), we finalized an exception to the drug designation process for calcimimetics. Specifically, we identified phosphate binders and calcimimetics as oral-only drugs and, in accordance with § 413.234(d), an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. We stated that under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category, so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and finalized in the CY 2016 ESRD PPS final rule that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the base rate to account for these drugs. We further stated that we intend to use notice-and-comment rulemaking to include the oral and non-oral forms of calcimimetics and phosphate binders in the ESRD PPS bundled payment after the payment of the TDAPA. We explained that when these drugs are no longer oral-only drugs, we will pay for them under the ESRD PPS using the TDAPA based on the payment methodologies in section 1847A of the Act for a period of at least 2 years.

Change Request 10065, Transmittal 1889 issued August 4, 2017, replaced by Transmittal 1999 issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018. As discussed previously, calcimimetics will be paid using the TDAPA for a minimum of 2 years until sufficient claims data for rate setting analysis is available for these products. Since payments have been made beginning January 1, 2018, a 2-year period would end December 31, 2019. We are still in the process of collecting utilization claims data for both the oral and non-oral form of calcimimetics, which will be used for a rate setting analysis. Therefore, in the CY 2020 ESRD PPS proposed rule, we stated that we will continue to pay for calcimimetics using the TDAPA in CY 2020 (84 FR 38347).

We also discussed in the proposed rule that in the CY 2019 ESRD PPS final rule (83 FR 56943), we stated that we would continue to pay the TDAPA using the pricing methodologies under section 1847A of the Act (which includes ASP+6 percent) until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. We noted that calcimimetics were the first drugs for which we paid the TDAPA (83 FR 56931), and increased Medicare expenditures by $1.2 billion in CY 2018. It is clear, therefore, that ESRD facilities are furnishing these innovative drugs. We explained in the CY 2019 ESRD PPS final rule (83 FR 56943) that one of the rationales for the 6 percent add-on to ASP has been to cover administrative and overhead costs. We also explained that the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56944).

As we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38347), we have provided the TDAPA for calcimimetics for 2-full years, and we believe that is sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. Therefore, we proposed that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, would be 100 percent of ASP. That is, we proposed to modify § 413.234(c) by removing the clause ''except that for calcimimetics it is based on the pricing methodologies under section 1847A of the Social Security Act.'' We stated that we believed this proposal strikes a balance between supporting ESRD facilities in their uptake of these products and limiting the financial burden that increased payments place on beneficiaries and Medicare expenditures. We also noted that this policy would be consistent with the policy finalized for all other new renal dialysis drugs and biological products in the CY 2019 ESRD PPS final rule (83 FR 56948).

In addition, we noted that our proposal to condition the application of the TDAPA on CMS's receipt of ASP data, discussed in section II.B.2.c of this final rule, would also apply with respect to calcimimetic products.

The public comments and our responses to the comments regarding our proposal to change the basis of payment for the TDAPA for calcimimetics are set forth below.

Comment: MedPAC supported the proposal and stated that there is good rationale to change the basis for the TDAPA from ASP plus 6 percent to ASP with no percentage add-on. MedPAC noted that the ASP plus 6 percent policy was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. While the policy never stated what cost the ''+6 percent'' was intended to cover, MedPAC noted that applying the policy to ESRD facilities is considerably different from reimbursing physicians. First, the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for ESRD facilities. If the intent of the ''+6 percent'' was to address acquisition price variation, MedPAC asserted that rationale is diminished for ESRD facilities. Second, MedPAC noted that the TDAPA is an add-on payment adjustment to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of renal dialysis drugs and biological products. Therefore, if the intent of the ''+6 percent'' was to address storage and administration costs, MedPAC believed these costs are already addressed through the ESRD PPS bundled payment and thus do not warrant the additional 6 percent.

A national dialysis association disagreed with MedPAC regarding ASP+6 in the ESRD facility setting. The commenter stated that while ASP+6 is used in physician reimbursement, it is also used across the Medicare program as the reimbursement standard for health care providers of all types, including providers that are much larger than ESRD facilities, such as large hospital systems. This commenter, along with another commenter, expressed that recommending that ESRD facilities be paid differently than other health care providers for the same pharmaceutical products runs counter to MedPAC's longstanding view that Medicare should pay similar rates for similar care.

A drug manufacturer and an LDO expressed similar beliefs as the national dialysis association, stating that CMS should maintain parity in reimbursement across other settings of care in which ASP-based reimbursement is provided at ASP plus

6 percent. One commenter noted that the 6 percent add-on is important for patient access in ESRD facilities, like other health care providers. The other commenter noted that other Medicare payment systems provide dispensing fees to recognize such costs, and the commenter believes ESRD facilities should be compensated for these costs as well.

An LDO and a drug manufacturer were disappointed with CMS' proposal to decrease the TDAPA for calcimimetics from ASP+6 to ASP+0. They noted that not all ESRD facilities can purchase a drug at the ASP and stated that this is particularly the case with calcimimetics. They also expressed concern that other policies, including the budget sequester, the 20 percent co-insurance exclusion from bad debt, and unpaid cost-sharing obligations by states, will result in TDAPA payments for calcimimetics far below the ASP. One association stated that cutting the TDAPA reimbursement for calcimimetics to ASP+0 would actually move the baseline reimbursement to, at best, ASP − 1.6 after application of the ongoing sequester.

A national dialysis stakeholder organization stated that given the amount of money attributed to the ESRD PPS functional categories other than anemia management, it is difficult to see how any dollars could be used to cover the administrative costs of calcimimetics or any other products. A drug manufacturer and a national dialysis organization noted that ESRD facilities, like other providers of Part B-covered drugs, rely on the 6 percent add-on to help cover the costs of acquiring and handling drugs, and in the case of the oral form of the calcimimetic, dispensing the drug.

Another commenter explained that ESRD facilities need the current 6 percent add-on amount to help pay for the expensive storage, packaging, and administration costs associated with products eligible for the TDAPA (which require facilities to ensure registered nurses are available because they administer calcimimetics to patients). For example, such costs include: Shipping medications to the patient's home, particularly for homecare and nursing home patients; pharmacy dispensing fees, especially in the case of the many small providers that do not have pharmacy licenses; storage and utility costs to account for the drug's refrigeration requirement; purchasing costs; rinse back procedures, which require a registered nurse and the facility ensuring that a registered nurse is on-site; pill usage accounting; and billing procedures and processes, among others. The commenter explained that these costs are especially challenging for small and independent providers to bear when considering the fact that they also generally experience less favorable drug acquisition pricing than LDOs with significant market advantage and negotiating power.

An LDO explained that it continues to face significant administrative and overhead costs resulting from the inclusion of the calcimimetics into the ESRD PPS via the TDAPA. The commenter stated that these costs not transitional as CMS asserts. The commenter explained that it incurs ongoing costs for staff training on clinical protocols as well as costs related to internal updates for clinical and financial systems. A national dialysis association provided similar comments, stating the operational costs associated with furnishing calcimimetics to ESRD beneficiaries, such as storing, handling, and dispensing the drugs, are ongoing for so long as the drugs are furnished under the ESRD PPS and that there is no mechanism through which ESRD facilities can address these costs without reimbursement.

A home dialysis association expressed concern regarding the ESRD facility costs associated with home dialysis patients. The commenter noted that according to their members, approximately 25 percent of patients, both home and in-center, take some form of calcimimetic drug. The commenter explained that for home dialysis patients, the costs associated with actually getting the drug to the patient is especially important given that they are not present in clinic as often as in-center patients. The commenter stated that ESRD facilities must spend considerable time and resources making certain that these patients have access to necessary medications, like calcimimetics. Two commenters stated that CMS made a commitment in the CY 2016 ESRD PPS final rule, and reiterated that commitment in subsequent rulemaking, that it would reimburse the TDAPA using the pricing methodologies under section 1847 of the Act, which includes ASP+6 percent, until sufficient claims data for rate setting analysis are available, but not for less than 2 years. The commenters noted CMS should maintain this commitment to pay the TDAPA for calcimimetics at ASP+6 percent for the duration of the TDAPA period.

Response: The TDAPA is an add-on payment adjustment under the ESRD PPS, and is not intended to be a mechanism to make separate payment for Part B drugs. Section 1842(o) of the Act, which specifies payment for drugs included in a physician's or supplier's bill that are not paid on a cost or prospective payment basis as otherwise provided under Part B, provides for payment using the methodologies under section 1847A of the Act. In our CY 2019 ESRD PPS final rule(83 FR 56948), we stated that ASP+0 would be the basis for the TDAPA prospectively for all new renal dialysis drugs and biological products effective January 1, 2020. We explained that calcimimetics were excluded from this policy and the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We also stated that we believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We noted that there is no clear statement from Congress as to why the payment allowance is required to be 106 percent of ASP (ASP+6) as opposed to any other value from 101 to 105 percent, and, as MedPAC discussed in its June 2015 report, there is no consensus among stakeholders. We further explained that we believe moving from pricing methodologies available under section 1847A of the Act (which includes ASP+6) to ASP+0 for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary co-insurance) and stakeholder concerns, including those about incentivizing use of high cost drugs in ESRD facilities.

We believe that we have flexibility under section 1881(b)(14)(D)(iv) of the Act to base the amount of the TDAPA on a methodology that is not based on a payment methodology under section 1847A of the Act. There is no requirement to use the payment methodologies under section 1847A of the Act for renal dialysis drugs under the ESRD PPS. As a result we have reconsidered the use of the ASP+6 percent methodology under section 1847A of the Act for the TDAPA for calcimimetics and proposed to use ASP+0 instead.

We agree with MedPAC that the ASP+6 percent policy was developed to reimburse physicians for the cost of drugs and that the TDAPA is an add-on payment adjustment to the ESRD PPS

base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. We appreciate MedPAC's support for this proposal and agree that ASP+0 is appropriate as the basis for the TDAPA for calcimimetics for CY 2020. For all of these reasons, we are finalizing the proposal without modification.

Comment: Some commenters explained that the ASP does not reflect the cost of many ESRD facilities who purchase products well above the ASP. An LDO noted that not all ESRD facilities can purchase a drug at the ASP and that this is particularly the case with calcimimetics. A drug manufacturer explained that the ASP is a market-based price that reflects the weighted average of all manufacturer sales prices and includes most rebates and discounts that are negotiated between manufacturers and purchasers in the commercial market. The manufacturer explained that not all health care providers receive the same discounts, therefore the manufacturer believes that the 6 percent add-on is important in ensuring patient access across providers. The commenter further explained that discounts provided to the supply chain—such as wholesalers—may be included in the ASP but may not be passed on to ESRD facilities.

Response: We understand the concerns expressed by the commenters about ASP, and the difficulties that may be encountered by small dialysis centers unable to negotiate the lower drug prices attributed to volume, and inaccessibility to supply chain discounts. The purpose of the TDAPA policy is not to offset business losses or to enhance business profits. The TDAPA is an add-on payment adjustment under the ESRD PPS, and is not intended to be a mechanism to make separate payment for Part B drugs. Section 1842(o) of the Act, which specifies payment for drugs included in a physician's or supplier's bill that are not paid on a cost or prospective payment basis as otherwise provided under Part B provides for payment using the methodologies under section 1847A of the Act. We do, however, continue to believe ASP data is the best data available for the purposes of determining the basis of payment for the TDAPA since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions. With regard to the importance of the six percent add-on, we continue to believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category.

Comment: Some commenters expressed concern that our proposal to base the TDAPA payments for calcimimetics at 100 percent of ASP for CY 2020 could jeopardize patient access to calcimimetics and have unintended consequences. One commenter stated that this would particularly affect patients treated by small and independent providers often in rural and underserved areas with limited resources and low to negative Medicare margins. A drug manufacturer commented that basing the TDAPA on ASP+0 would disincentivize the adoption of innovative new therapies and that policies designed to facilitate patient access to innovative new therapies should not reduce the add-on payment to the ASP that ensures providers are able to deliver these medicines to patients.

An LDO expressed concern that ESRD facilities will be forced to choose between ceasing to provide the calcimimetics or losing additional money every time they provide calcimimetics. The LDO also expressed concern that the proposal could inhibit generic drug adoption and encourage utilization of the branded IV calcimimetic at great expense to the Medicare program and its beneficiaries. The LDO stated that it is committed to providing patients with the most cost-effective option for treatment, which typically results in prioritizing oral generic drugs and reserving the IV option for patients who otherwise fail to respond to treatment on the oral form. However the LDO strongly urged CMS to consider that, at ASP+0, many providers will lose money on cinacalcet, which could incentivize a shift in first line treatment to the IV version at a much greater cost to the program. A national dialysis association expressed similar concerns, stating that the proposal could incentivize use of the IV calcimimetic over the generic oral calcimimetic as ESRD facilities grapple with choosing the product for which they will lose the least amount of money due to declining reimbursement.

An LDO expressed concern that shifting the basis of payment in the middle of the TDAPA period for calcimimetics could skew the utilization and claims data used to inform post-TDAPA payment and that CMS should continue payment at 106 percent of ASP during the third year of TDAPA to ensure payment adequacy and consistency in utilization data it is collecting.

Response: As noted previously, we continue to believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We further believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products. Regarding the concern that reducing the basis of TDAPA payment to ASP+0 for calcimimetics will steer ESRD facilities toward not providing the drug, or toward providing an alternative form of the drug, we believe that physicians and their patients should make the decision together on the appropriate form of the drug for treatment. It is not our intent to interfere with that decision making process. As the number of drugs within each functional group increases and market share competition from the manufacturers is a factor, we anticipate easier access, more choices in care and lower prices. We acknowledge that payment policies may have unintended consequences as identified by the commenters, however, it is our expectation that ESRD facilities will follow the physician's plan of care for the patient and we will closely monitor drug utilization at the beneficiary and facility level for these types of issues.

With respect to the concern that reducing the basis of payment to ASP+0 for calcimimetics will complicate the data we will use when considering whether to modify the base rate at the end of the TDAPA period, we are currently evaluating potential methodologies for this purpose. There are a number options being discussed as a result of stakeholder input and at the time we undergo rulemaking, we will analyze the data available and input received from stakeholders when developing our proposal to incorporate these products into the ESRD PPS base rate.

Comment: Several commenters stated that CMS has indicated in previous rules that the ESRD PPS base rate does not include administrative costs associated with dispensing oral drugs. One commenter noted in addition to the small dollar amounts allocated to drugs in most ESRD PPS functional categories,

CMS has stated that the base rate does not include the cost of oral-only drugs. Another commenter stated that while CMS indicates that the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products, this statement contradicts CMS' earlier statement regarding calcimimetics that dollars were never included in the base rate to account for these drugs. The commenter noted that CMS acknowledged there are no dollars in the base rate for calcimimetics and therefore cannot assert that there are dollars in the base rate available to cover administration and overhead related to calcimimetics.

Response: As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56944 through 56946), with regard to the concerns that ASP+0 will not cover the administrative costs associated with bringing a new drug or biological product as a therapeutic option in a facility, we pointed out that under the current ESRD PPS, new renal dialysis drugs that are considered to be in a functional category would not receive any additional payment. Payment for these drugs has been included in the ESRD PPS bundled payment amount since the inception of the ESRD PPS. There is no clear reason for the 6 percent add-on, and, as MedPAC discussed in its June 2015 report, there is no consensus among stakeholders on the purpose of the 6 percent add-on. We further explained that we believe moving from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0 for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary co-insurance) and stakeholder concerns discussed in section II.B.1.e of the CY 2019 ESRD PPS final rule. We note that since January 1, 2018, ESRD facilities have been receiving the TDAPA for calcimimetics at ASP+6 as part of the ESRD PPS payment amount. We continue to believe that 2 full years of paying the TDAPA at ASP+6 is sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics.

Comment: A national dialysis association explained that its review of the publicly available data on Medicare's spending on calcimimetics indicates that Medicare spending has decreased under the TDAPA as compared to prior payment policies. The commenter explained that in CY 2017, prior to CMS moving calcimimetics from Medicare Part D to the ESRD PPS under Part B, CMS spent more than $1.4 billion on calcimimetics. Between 2013 and 2017, the price per unit of calcimimetics increased by an average of 15 percent each year, compared to an average increase in patients utilizing calcimimetics of 6 percent each year. The commenter asserted that had these trends continued, CMS would have paid almost $1.8 billion for calcimimetics in Part D in CY 2018. The commenter acknowledged that the Part D data set includes all beneficiaries using calcimimetics and not just those with ESRD, but noted that majority of beneficiaries using calcimimetics are ESRD beneficiaries. The commenter stated that it cannot identify a data source that supports CMS' claim of a $1.2 billion increase in Medicare spending on calcimimetics in CY 2018. On the contrary, the commenter's review of the data indicates that Medicare spending on calcimimetics decreased under the TDAPA from more than $1.4 billion in CY 2017 to $1 billion represented in the file containing 85 percent of the claims in CY 2018. The commenter believes that that because calcimimetics moved from Part D spending to Part B spending in CY 2018, that CMS should not claim an increase in Part B spending. The commenter stated that if there is another source of data that the public should review in order to fully evaluate CMS' claims, then that data should be made available along with the rulemaking. The commenter further asserted that if CMS's statement of an increase in Medicare spending on calcimimetics is not correct or corroborated by the data, it is not adequate justification for the proposal to change reimbursement for the TDAPA for calcimimetics from ASP+6 to ASP+0 and CMS should not finalize this proposal.

Response: In response to the commenter's questions about the $1.2 billion increase in Medicare costs for calcimimetics, we clarify that the $1.2 billion figure refers to expenditures under the ESRD PPS for CY 2018, as reflected in claims, due to the utilization of calcimimetics alone.

We do not believe that it is appropriate to consider expenditures in other Medicare or Medicaid funding areas when developing policies under the ESRD PPS. These funding areas are not co-mingled or mutually interchangeable. In addition, the Part B spending includes the injectable form of the calcimimetic which was not covered under Part D. We have further reviewed our data for CY 2018 and stand by the stated 1.2 billion increase to ESRD PPS expenditures.

Final Rule Action: After careful consideration of public comments, we are finalizing our proposal that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, will be 100 percent of ASP. Specifically, we are finalizing the proposed modification to § 413.234(c) by removing the clause ''except that for calcimimetics it is based on pricing methodologies under section 1847A of the Social Security Act.''

e. Revision to 42 CFR 413.230

In the CY 2011 ESRD PPS final rule (75 FR 49200), we added § 413.230 to 42 CFR part 413, subpart H to codify that the per treatment payment amount is the sum of the per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235; any outlier payment under § 413.237; and any training adjustment add-on under § 414.335(b). The per treatment payment amount is Medicare's payment to ESRD facilities under the ESRD PPS for furnishing renal dialysis services to Medicare ESRD beneficiaries.

In the CY 2016 ESRD PPS final rule (80 FR 69024), we codified the drug designation process regulation in § 413.234, which provides a TDAPA under § 413.234(c) when certain eligibility criteria are met. We apply the TDAPA at the end of the calculation of the ESRD PPS payment, which is similar to the application of the outlier payment (§ 413.237(c)) and the training add-on adjustment (§ 413.235(c)). That is, once the ESRD PPS base rate is adjusted by any applicable patient- and facility-level adjustments we add to it any applicable outlier payment, training add-on adjustment, or TDAPA.

In CY 2016 ESRD PPS rulemaking, we did not propose a corresponding revision to § 413.230 to reflect that the TDAPA is a component in the determination of the per treatment payment amount. Therefore, in the CY 2020 ESRD PPS proposed rule (84 FR 38347), we proposed a revision to § 413.230 to add paragraph (d) to reflect the TDAPA. We stated that we believed this modification is necessary so that the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount. We noted that this revision to the regulation would not change how the ESRD PPS per treatment payment amount is currently calculated. We also proposed

to revise § 413.230 to include, as part of the calculation of the per treatment payment amount, any TPNIES as discussed in section II.B.3.b.iii of this final rule.

We also proposed a technical change to § 413.230(c) to replace ''§ 414.335(b)'' with a more appropriate reference to the training adjustment add-on requirement, which is ''§ 413.235(c).'' In the CY 2011 ESRD PPS final rule (75 FR 49202) we inadvertently referred to § 414.335(b), which states, ''After January 1, 2011, a home and self-training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230'' when finalizing § 413.230. Section 413.235(c) similarly states ''CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.'' However, as we explained in the CY 2020 ESRD PPS proposed rule, § 414.335(b) describes the training adjustment add-on when erythropoietin (EPO) is furnished to home dialysis patients, whereas § 413.235(c) describes the application of the training adjustment add-on more generally, even when EPO is not furnished. When we finalized § 413.230 in the CY 2011 ESRD PPS final rule, we intended for the training adjustment add-on to apply more generally, not just when EPO is furnished, and therefore we are proposing to refer to § 413.235(c).

We did not receive any comments on our proposal for technical changes to § 413.230. Therefore, we are finalizing the changes as proposed.

2. Average Sales Price (ASP) Conditional Policy for the TDAPA

a. Background

In the CY 2005 Physician Fee Schedule (PFS) final rule, published on November 15, 2004 (69 FR 66299 through 66302) in the **Federal Register**, we discussed that section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1847A to the Act and established a payment methodology for certain drugs and biological products not paid on a cost or prospective payment basis furnished on or after January 1, 2005. Payments made under this methodology are primarily based on quarterly data submitted to CMS by drug manufacturers, and most payments under this methodology are based on the ASP. ASP-based payments are determined from manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of ''best price'' in the Medicaid Drug Rebate Program. ASP-based payments are determined for individual HCPCS codes. To allow time for manufacturers to submit quarterly data and for CMS to determine, check and disseminate payment limits to contractors that pay claims, the ASP-based payment limits are subject to a 2 quarter lag, which means that sales from January to March are used to determine payment limits in effect from July to September.[20]

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the drug products included in the HCPCS code. Section 1847A(b)(1)(B) of the Act also requires that the Medicare payment for a single source drug HCPCS code be equal to the lesser of 106 percent of the ASP for the HCPCS code or 106 percent of the Wholesale Acquisition Cost (WAC) of the HCPCS code (83 FR 56929). The WAC is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Section 1847A(c)(4) of the Act further provides a payment methodology in cases where the ASP during 1st quarter of sales is unavailable, stating that in the case of a drug or biologicals during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological product are not sufficiently available from the manufacturer to compute an ASP for the biological product, the Secretary may determine the amount payable under this section for the drug or biological product based on the WAC or the methodologies in effect under Medicare Part B on November 1, 2003, to determine payment amounts for drugs or biological products. For further guidance on how Medicare Part B pays for certain drugs and biological products, see Medicare Claims Processing Manual (Pub. L. 100–04) (chapter 17, section 20) (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf*).

[20] ASPE. Issue Brief. Medicare Part B Drugs: Pricing and Incentives. March 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf.*

We have used the payment methodology under section 1847A of the Act since the implementation of the ESRD PPS when pricing ESRD related drugs and biological products previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations (82 FR 50742 through 50743). In the CY 2016 ESRD PPS final rule (80 FR 69024), we adopted § 413.234(c), which requires that the TDAPA is based on payment methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such payment methodologies for Part B ESRD related drugs or biological products that qualify as an outlier service (82 FR 50745). For the purposes of the ESRD PPS, we use ''payment methodology'' interchangeably with ''pricing methodology.''

In the CY 2019 ESRD PPS final rule (83 FR 56948) we finalized a revision to § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to base the TDAPA on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We also explained in the CY 2019 ESRD PPS final rule (83 FR 56944) that there are times when the ASP is not available. For example, when a new drug or biological product is brought to the market, sales data is not sufficiently available from the manufacturer to compute an ASP. Therefore, we finalized a change to § 413.234(c) to specify that if ASP is not available, the TDAPA is based on 100 percent of WAC (WAC+0) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. We also modified § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We specified that these changes to § 413.234(c) would be effective January 1, 2020.

In the CY 2019 ESRD PPS final rule (83 FR 56943), we discussed that the TDAPA is a payment adjustment under the ESRD PPS and is not intended to be a mechanism for payment for new drugs and biological products under Medicare Part B. We further explained that we believe it may not be appropriate under section 1881(b)(14)(D)(iv) of the Act to base the TDAPA strictly on the pricing methodologies under section 1847A of the Act. We explained that, in the CY 2019 ESRD PPS proposed rule (83 FR 34315), we considered options on which to base payment under the TDAPA, for example, maintaining the policy as is or

potentially basing payments on the facility cost of acquiring drugs and biological products. We found that while the pricing methodologies under 1847A of the Act, and specifically ASP, could encourage certain unintended consequences, ASP data continues to be the best data available since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions (83 FR 34315).

b. Basis for Conditioning the TDAPA on the Availability of ASP Data

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38348), under the change to § 413.234(c) finalized in the CY 2019 ESRD PPS final rule (83 FR 56948), effective January 1, 2020, the basis of payment for the TDAPA is ASP+0, but if ASP is not available, then it is WAC+0, and if WAC is not available, then it is based on the drug manufacturer's invoice. In the CY 2019 ESRD PPS final rule, we also modified § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). As discussed in section II.B.1.d of the CY 2020 ESRD PPS proposed rule (84 FR 38330) and section II.B.1.d of this final rule, we proposed to modify the basis of payment for the TDAPA for calcimimetics for CY 2020 to ASP+0.

In the CY 2020 ESRD PPS proposed rule (84 FR 38348 through 38349), we discussed that, following publication of the CY 2019 ESRD PPS final rule, we continued to assess our policy allowing for WAC or invoice pricing if ASP is not available, and became concerned that it could lead to drug manufacturers who are not otherwise required to submit ASP data to CMS to delay submission or withhold ASP data from CMS so that ESRD facilities would receive a higher basis of payment for the TDAPA and be incentivized to purchase drugs from those manufacturers.

We stated that calcimimetics were the first drugs for which we paid the TDAPA (83 FR 56931), and this increased Medicare expenditures by $1.2 billion in CY 2018. We noted that the TDAPA for one form of the calcimimetics was based on WAC for 2 quarters, and was more expensive than ASP. In addition, there were delays in the submission of ASP data for that drug, but we are now receiving ASP data for both calcimimetics. We explained that we were concerned about the significant increase in Medicare expenditures that resulted from paying the TDAPA for calcimimetics, and about this trend continuing with new renal dialysis drugs and biological products that become eligible for the TDAPA in the future. We therefore believed we needed to limit the use of WAC (or invoice pricing) as the basis of the TDAPA to as few quarters as practicable to help limit increases to Medicare expenditures while maintaining our goals for the TDAPA policy—namely, supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products for those products that fall within a functional category and providing a pathway towards a potential base rate modification for those products that do not fall within a functional category.

We also noted that we were concerned that ASP will not be made available to CMS by drug manufacturers not currently required by statute to do so. Drug manufacturers who have Medicaid Drug Rebate Agreements as part of the Medicaid Drug Rebate Program are required by section 1927(b)(3) of the Act to submit ASP sales data into CMS quarterly. However, we anticipated there could be drugs marketed in the future that are eligible for the TDAPA, but may not be associated with ASP reporting requirements under section 1927(b) of the Act. While manufacturers that do not have Medicaid Drug Rebate Agreements may voluntarily submit ASP data into CMS,[21] we stated that we were concerned manufacturers may not elect to do so. MedPAC and the Office of the Inspector General (OIG) have both noted concerns about manufacturers not reporting ASP data for Part B drugs. As discussed in MedPAC's June 2017 Report to Congress,[22] the OIG found that for the 3rd quarter of 2012, out of 45 drug manufacturers who were not required to submit ASP for Part B drugs, only 22 voluntarily submitted ASP data.[23]

We pointed out that even for those drug manufacturers who are required to submit ASP data into CMS, not all may fully comply. For the same 3rd quarter of 2012, the OIG found that at least 74 out of the 207 drug manufacturers with Medicaid Drug Rebate Agreements in place did not submit all of their required ASP data for their Part B drugs.[24] MedPAC's recommendations in its June 2017 report [25] would require that all Part B drug manufacturers submit ASP data into CMS, whether or not those manufacturers have a Medicaid Drug Rebate Agreement. Based on this data and our own experience with the calcimimetics, we expressed concern that manufacturers may not voluntarily report ASP data into CMS. We noted that we continue to believe that ASP is the best data currently available for the basis of payment for the TDAPA, because it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions (83 FR 56943). Therefore, we stated that we believed conditioning the TDAPA on the availability of ASP data is appropriate and necessary to ensure that we are basing the amount of the TDAPA on the best data available.

We noted in the CY 2020 ESRD PPS proposed rule (84 FR 38349) that, in addition to our concerns about ASP data reporting generally, we were concerned that the TDAPA policy finalized in the CY 2019 ESRD PPS final rule effective January 1, 2020, could potentially incentivize drug manufacturers who do not have a Medicaid Drug Rebate Agreement to delay or to never submit ASP data in order for ESRD facilities to receive an increased TDAPA for their products. As noted in section II.B.2.a of the CY 2020 ESRD PPS proposed rule, under § 413.234(c), effective January 1, 2020, if ASP is not available to CMS, the basis of payment for the TDAPA is WAC+0 and when WAC is not available, then the TDAPA is based on invoice pricing. As MedPAC discussed in its June 2017 Report to Congress, WAC-based payments would likely increase Medicare expenditures as compared to ASP-based payments. As stated in section 1847A(c)(5) of the Act, ASP is calculated to include discounts and rebates. WAC is ultimately controlled by the manufacturer, and its statutory definition in section 1847A(c)(6)(B) of the Act does not include the discounts

[21] MedPAC. Part B Drugs Payment Systems. October 2017. Page 2. Available at: *http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0*.

[22] Report to Congress, MedPAC, June 2017, page 42. Available at: *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf*.

[23] Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, Office of the Inspector General, page 7. Available at: *https://oig.hhs.gov/oei/reports/oei-12-13-00040.pdf*.

[24] Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, Office of the Inspector General, pages 7–8, Available at: *https://oig.hhs.gov/oei/reports/oei-12-3-00040.pdf*.

[25] Report to Congress, MedPAC, June 2017, pages 10–12. Available at: *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf*.

that ASP includes.[26] Similarly, invoice pricing may not reliably capture all available discounts and thus may be inflated. This means if a drug manufacturer chooses not to submit ASP data into CMS, the TDAPA would be based on an inflated amount beyond what the average cost to ESRD facilities to acquire those drugs. This additional amount would also then increase the co-insurance for the beneficiaries who receive those drugs. We explained in the CY 2020 ESRD PPS proposed rule that we believed conditioning the TDAPA on the availability of ASP data is necessary to mitigate this potential incentive and limit increases to Medicare expenditures.

c. Proposal To Condition the TDAPA Application on the Availability of ASP Data

In the CY 2020 ESRD PPS proposed rule (84 FR 38349), we proposed to revise § 413.234(c) to address the following concerns: (1) Increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for the TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS. Under our proposed revisions, we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin paying the TDAPA for the product. We noted in the CY 2020 ESRD PPS proposed rule that we were not proposing to modify the current ASP reporting process [27] and our proposals were consistent with this process. Since it is possible for a drug manufacturer to begin sales of its product in the middle of a calendar quarter, it may take approximately 2 to 3 quarters for CMS to obtain a full calendar quarter of ASP data. We explained in the CY 2020 ESRD PPS proposed rule that we believed that 3-calendar quarters is a reasonable amount of time for drug manufacturers to submit a full calendar quarter of ASP data to CMS; therefore, we proposed to allow 3-calendar quarters for drug manufacturers to make ASP available to CMS to enable ESRD facilities to continue to receive the TDAPA for a product.

As we discussed in section II.B.2.a of the CY 2020 ESRD PPS proposed rule, there is a 2 quarter lag between the sales period for which ASP is reported and the effective date of the rate based on that ASP data. During this period between when the TDAPA is initiated for a product and the effective date of the rate based on the full quarter of ASP data made available to CMS, consistent with the policy finalized in the CY 2019 ESRD PPS final rule (83 FR 56948), the basis of the TDAPA would be WAC+0, and if WAC is not available, then invoice pricing. Once the drug manufacturer begins submitting ASP data, the basis of the TDAPA would be ASP+0. We proposed that if we have not received a full calendar quarter of ASP data for a new renal dialysis drug or biological product by 30 days after the last day of the 3rd calendar quarter of applying the TDAPA for that product, we would stop applying the TDAPA within the next 2-calendar quarters. For example, if we begin applying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data for that product has not been made available to CMS by October 30, 2021 (30 days after the last day of the 3rd quarter of paying the TDAPA), we would stop applying the TDAPA for that product no later than March 31, 2022 (2 quarters after the 3rd quarter of paying the TDAPA).

We therefore proposed to revise the regulatory text at § 413.234(c) to provide that, notwithstanding the time periods for payment of the TDAPA specified in paragraphs (c)(1) and (c)(2), we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS has not received a full calendar quarter of ASP data for the product within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product.

We noted in the CY 2020 ESRD PPS proposed rule that we expect that once drug manufacturers begin submitting ASP data into CMS, they would continue to do so for the duration of the TDAPA period as set forth in § 413.234(c). We explained that we continue to believe that basing the TDAPA on ASP+0, as compared to WAC+0 or invoice pricing, is the most appropriate choice for the ESRD PPS, and strikes the right balance of supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. We stated that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on WAC or invoice pricing, we believed we would be overpaying for the TDAPA for those products.

Therefore, we also proposed to revise the regulatory text at § 413.234(c) to state that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the close last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (c)(2), stops submitting a full calendar quarter of ASP data into CMS. We explained that we assess pricing for new renal dialysis drugs and biological products eligible for the TDAPA on a quarterly basis. Under our proposal, once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, if we begin paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

The comments and our responses to the comments on our proposal to implement an ASP conditional policy for application of the TDAPA are set forth below.

Comment: Several commenters stated that it is unfair to impose this condition on the TDAPA because it would reduce the payment amount provided to ESRD facilities, while it is the manufacturers who are responsible for submitting the ASP data into CMS. One LDO noted that ESRD facilities have no ability to influence whether a manufacturer submits ASP data into CMS, while another LDO further argued that CMS does not have the authority to impose this condition on the TDAPA since the facilities do not have control over whether the ASP data is submitted into CMS by the manufacturer.

Response: We have authority under section 1881(b)(14)(D)(iv) of the Act to include under the ESRD PPS such other

[26] MedPAC. Part B Drugs Payment Systems. October 2017. Pages 43–44. Available at: *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.*

[27] CMS. Medicare Part B Drug Average Sales Price. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

payment adjustments as the Secretary determines appropriate, and we established the TDAPA for new renal dialysis drugs and biological products under this authority. We also have authority to place conditions on those payment adjustments, as we have otherwise done for the TDAPA by requiring that the renal dialysis drug or biological product meet certain eligibility criteria under § 413.234. As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38349), we are concerned about (1) increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS. We believe conditioning the TDAPA on the availability of ASP data is appropriate and necessary to address these concerns and ensure that we are basing the amount of the TDAPA on the best data available to address these concerns, and not overpaying through WAC or invoice pricing. In addition, we do not believe that this policy is unfair because we believe that ESRD facilities have the ability to influence drug manufacturers to submit ASP data due to the manufacturers' desire to have market share. With more choices available through the ESRD PPS functional categories, drug manufacturers may want to retain or capture more market share with their products as competition increases. ESRD facilities are able to have discussions with drug manufacturers as to whether they reported the ASP into CMS and, if not, when they plan to do so.

Comment: A drug manufacturer and an LDO stated that we should only apply this policy on an individual basis, that is, if a drug is multi-source, meaning available from a brand-name drug manufacturer and also from other manufacturers, we should not penalize all manufacturers of the drug if one manufacturer fails to submit ASP data. The drug manufacturer further asked us to clarify whether the ASP conditional policy will apply to payments made on or after 2020 or to ASP data reported in 2020.

Response: First, we would like to reassure the commenters that the intent of our proposal was to apply this policy on an individual product basis. That is, under the revisions to § 413.234(c), we would condition the TDAPA for an individual renal dialysis drug or biological product on the availability of ASP data for that product. We would not condition the TDAPA for an individual drug or biological product on the availability of ASP data from all manufacturers of that drug or biological product. For example, if drug X is manufactured by manufacturer A and manufacturer B and manufacturer A does not make ASP data available to CMS but manufacturer B does, we would not apply the ASP conditional policy to manufacturer B's drug. That is, the ESRD facility would not receive the TDAPA when reporting on ESRD facility claims drug X from manufacturer A.

With regard to whether the ASP conditional policy will apply to payments made on or after January 1, 2020 or to ASP data reported in 2020, we note that this policy would become effective January 1, 2020. Therefore, for a renal dialysis drug or biological product for which we are currently paying the TDAPA and for which ASP data is currently being reported, beginning January 1, 2020, if CMS does not receive the latest full calendar quarter of ASP data for the product, CMS will no longer apply the TDAPA beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

Comment: Several commenters were concerned that this policy could create consequences such as increased costs to ESRD facilities, which is particularly problematic for small and independent facilities, and could lead to facilities choosing not to furnish those drugs or biological products, which could decrease access for their patients. One commenter also argued this policy would complicate the collection of utilization data and thereby negatively affect how these drugs and biological products would be incorporated into the ESRD PPS bundled payment. Another commenter asserted that this proposal would impact the continuity of patient care and cause confusion in the billing and ordering process. A national dialysis stakeholder organization stated that it did not believe this policy would actually increase ASP reporting as it is intended to do.

Response: We understand the commenters' concerns. However, we continue to be concerned that drug manufacturers who are not otherwise required to submit ASP data to CMS would delay submission or withhold ASP data from CMS so that ESRD facilities would receive a higher basis of payment for the TDAPA and be incentivized to purchase drugs from those manufacturers. Additionally, we believe that this policy will incentive ASP reporting and ESRD facilities will want to provide the new renal dialysis drugs and biological products that are eligible for the TDAPA to their patients. We expect that, as the number of drugs and biological products within each ESRD PPS functional category increases and market share competition from the manufacturers is a factor, there would be easier access, more choices in care and lower prices.

Comment: Several commenters recognized the issue of underreporting of ASP data that CMS was trying to solve, but preferred that CMS use other mechanisms to enforce ASP reporting. One commenter suggested CMS use Average Manufacturer Price (AMP) after a certain period of time of ASP not being reported. One drug manufacturer suggested that we allow a temporary deferment or exclusion from the ASP conditional policy when manufacturers encounter extraordinary circumstances beyond their control.

Response: We thank the commenters for their suggestions. We have the same concern with AMP as we do with WAC and invoice pricing in that it is more expensive than ASP. We continue to believe ASP data is the best data available for the purposes of the TDAPA since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions. We also believe that our policy provides sufficient time to deal with extraordinary circumstances, so it is not necessary to establish that type of exception. However, we will monitor the effects of this proposal and consider these suggestions for future rulemaking.

Comment: One LDO suggested that CMS's motivation for proposing this policy was the perception that ESRD facilities were putting financial gain over the wellbeing of the patients. The LDO explained that when the new IV and generic oral calcimimetics became available the LDO followed the guiding principle that patients deserve access to the formulation that best meets their needs, while also remaining mindful of overall system costs.

Response: We appreciate that the commenter is focused on providing its patients with access to formulations that best meet their clinical needs. However, we believe the comment about our motivation for this policy is unfounded. As noted previously, we based this proposal on our concerns about (1) increases to Medicare expenditures due to TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for drugs eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS.

Comment: MedPAC and a non-profit provider association were supportive of conditioning the TDAPA on the availability of ASP data. Both suggested CMS consider going further by either requiring all Part B drug manufacturers to report ASP data, or by not applying the TDAPA to all eligible drugs from a noncompliant manufacturer rather than just the new renal dialysis drug or biological product for which the manufacturer is not reporting ASP data.

One national dialysis association supported MedPAC's suggestion that CMS take steps to ensure manufacturers report ASP data. However, the association specifically disagreed with MedPAC that CMS should require all Part B drug manufacturers report ASP data and believed any such requirement should be imposed directly on drug manufacturers under CMS authorities, and not on ESRD facilities.

Response: We have authority under section 1881(b)(14)(D)(iv) of the Act to include under the ESRD PPS such other payment adjustments as the Secretary determines appropriate, and we established the TDAPA for new renal dialysis drugs and biological products under this authority. We also have authority to place conditions on those payment adjustments, as we have otherwise done for the TDAPA by requiring that the renal dialysis drug or biological product meet certain eligibility criteria under § 413.234. At this time, we believe this policy appropriately targets the condition on the particular renal dialysis drug or biological product for which CMS has not received ASP data. We will take these suggestions under consideration for future rulemaking.

Comment: A national dialysis association explained that its review of the publicly available data on Medicare's spending on calcimimetics indicate that Medicare spending has decreased under the TDAPA as compared to prior payment policies. The commenter stated that it cannot identify a data source that supports CMS' claim of a $1.2 billion increase in Medicare spending on calcimimetics in CY 2018. On the contrary, the commenter's review of the data indicates that Medicare spending on calcimimetics decreased under the TDAPA from more than $1.4 billion in CY 2017 to $1 billion represented in the file containing 85 percent of the claims in CY 2018. The commenter believes that because calcimimetics moved from Part D spending to Part B spending in CY 2018, that CMS should not claim an increase in Part B spending. The commenter stated that if there is another source of data that the public should review in order to fully evaluate CMS' claims, then that data should be made available along with the rulemaking. The commenter further asserted that as CMS's statement of an increase in Medicare spending on calcimimetics is not correct or corroborated by the data, it is not adequate justification for the proposal to condition the TDAPA on the provision of ASP data.

An LDO noted the decrease in expenditures due to calcimimetics discussed in the comment from the national dialysis association and stated that the data was inconsistent with CMS' analysis in the proposed rule.

Response: In response to the commenter's questions about the $1.2 billion increase in Medicare costs for calcimimetics, we clarify that the $1.2 billion figure refers to expenditures under the ESRD PPS for CY 2018, as reflected in claims, due to the utilization of calcimimetics alone. We do not believe that it is appropriate to consider expenditures in other Medicare or Medicaid funding areas when developing policies under the ESRD PPS. These funding areas are not co-mingled or mutually interchangeable. In addition, the Part B spending includes the injectable form of the calcimimetic which was not covered under Part D. We have further reviewed our data for CY 2018 and stand by the stated 1.2 billion increase to ESRD PPS expenditures.

Final Rule Action: After consideration of public comments, we are finalizing the ASP conditional policy as proposed, effective January 1, 2020. Under our final policy, the basis of payment for the TDAPA for all new renal dialysis drugs and biological products is ASP+0, but if ASP is not available then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice. We are revising § 413.234(c) to state that notwithstanding the provisions in paragraphs (c)(1) and (2) of that section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for the product, CMS will no longer apply the TDAPA for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. In addition, if CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of § 413.234, CMS will no longer apply the TDAPA for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

3. New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

a. Background on Renal Dialysis Equipment and Supplies Under the ESRD PPS

In the CY 2011 ESRD PPS final rule (75 FR 49075), we stated that when we computed the ESRD PPS base rate, we used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate. These are identified in Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as ''Composite Rate Services''. Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. As we indicated in the CY 2011 ESRD PPS proposed rule (74 FR 49928), the case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). In the CY 2011 ESRD PPS final rule (75 FR 49062), we noted that total composite rate costs in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs.

Currently, ESRD facilities are required to report their use of syringes on claims in order to receive separate payment, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49141). However, historically, ESRD facilities were not required to report any other renal dialysis equipment and supplies on claims (with the exception of syringes) because these items were paid through the composite rate and did not receive separate payment. As discussed in the Medicare Claims Processing Manual (chapter 8, section 50.3), CMS directs ESRD facilities to report a dialysis treatment and their charge for the treatment. That charge is intended to reflect the cost of the dialysis treatment (equipment, supplies, and staff time) as well as routine drugs and laboratory tests. This manual is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf.*

In the CY 2019 ESRD PPS final rule (83 FR 56942 through 56943), we finalized an expansion of the TDAPA to all new renal dialysis drugs and biological products. As part of the CY 2019 ESRD PPS rulemaking, we received several comments regarding payment under the ESRD PPS for certain new, innovative equipment and supplies used in the treatment of ESRD. For example, as we described in the CY 2019 ESRD PPS final rule (83 FR 56972), a device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new devices that have been granted marketing authorization by FDA. They commented on the lack of new devices granted marketing authorization by FDA for use in an ESRD facility, highlighting the need to promote dialysis device innovation. The commenters indicated they believed the same rationale CMS used to propose broadening the TDAPA eligibility also would apply to new devices. Specifically, the commenters noted that CMS has discretionary authority under section 1881(b)(14)(D)(iv) of the Act to adopt payment adjustments determined appropriate by the Secretary, and stated that precedent supports CMS' authority to use non-budget neutral additions to the ESRD PPS base rate for adjustments under specific circumstances.

A professional association urged CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the ESRD PPS bundled payment (83 FR 56973). The association stated that additional money should be made available to appropriately reflect the costs of new devices under the ESRD PPS bundled payment. A national dialysis organization and a large dialysis organization (LDO) asked CMS to clarify how it incentivizes the development of new dialysis devices. The organization asked CMS to describe how such a device would be included in the ESRD PPS bundle, and suggested the initial application of a pass-through payment, which would be evaluated later based on the data. The organization stated that this evaluation would determine if the device should be included in the ESRD PPS base rate and whether or not additional funds should be added to the ESRD PPS bundled payment.

In addition, as we discussed in the CY 2019 ESRD PPS final rule (83 FR 56973), an LDO requested CMS plan appropriately for innovative devices or other new and innovative products and asked CMS to work with the kidney care community to consider if and how new devices or other new and innovative products delivering high clinical value, can be made available to beneficiaries, whether through the ESRD PPS or through other payment systems. A home dialysis patient group also expressed concern regarding the absence of a pathway for adding new devices to the ESRD PPS bundled payment, stating that it left investors and industry wary of investing in the development of new devices for patients. In response to these comments, we expressed appreciation for the commenters' thoughts regarding payment for new and innovative devices, and stated that we did not include any proposals regarding this issue in the CY 2019 ESRD PPS proposed rule, so we considered these suggestions to be beyond the scope of that rule.

Also, in the CY 2019 ESRD PPS proposed rule, we solicited comment on whether we should expand the outlier policy to include composite rate drugs and supplies (83 FR 34332). We noted that under the proposed expansion to the drug designation process, such expansion of the outlier policy could support appropriate payment for composite rate drugs once the TDAPA period has ended. Additionally, with regard to composite rate supplies, an expansion of the outlier policy could support use of new and innovative devices or items that would otherwise be considered in the ESRD PPS bundled payment. We stated that if commenters believe such an approach is appropriate, we requested they provide input on how we would effectuate such a shift in policy. For example, we noted, the reporting of these services may be challenging since they have never been reported on ESRD claims previously. We specifically requested feedback about how such items might work under the existing ESRD PPS outlier framework or whether specific changes to the policy to accommodate such items are needed.

We received mixed feedback in response to the comment solicitation, which was summarized in the CY 2019 ESRD PPS final rule (83 FR 56969 through 56970). Some LDOs and national dialysis organizations stated that they would prefer a smaller outlier pool with more money in the per treatment base rate while other ESRD facilities agreed that the outlier policy should be more comprehensive and expanded to include more items and services. In our response, we stated we recognized that the commenters' concerns regarding the expansion of outlier eligibility to include composite rate drugs and supplies are inextricably linked to their views on the effectiveness of our broader outlier policy or other payment adjustments. We indicated we would take these views into account as we consider the outlier policy and payment adjustments for future rulemaking.

In light of these comments, in the CY 2020 ESRD PPS proposed rule (84 FR 38350 through 38357), we considered whether additional payment may be warranted for certain new and innovative renal dialysis equipment and supplies. In the CY 2020 ESRD PPS proposed rule, we provided a general description of the IPPS new technology add-on payment (NTAP) and its SCI criteria, and we include that description again in sections II.B.3.a.i and II.B.3.a.ii of this final rule. We stated that we believe a process similar to the IPPS process for establishing SCI for the NTAP could be used to identify the innovative renal dialysis equipment and supplies for which commenters were requesting additional payment under the ESRD PPS. We noted that we believed an NTAP-like payment adjustment under the ESRD PPS would be appropriate in order to support innovation while being responsive to stakeholders.

i. Add-On Payments for New Technology Under the Inpatient Prospective Payment System

In the CMS Innovators' Guide to Navigating Medicare,[28] we explain that the hospital IPPS makes payments to acute care hospitals for each Medicare patient or case treated. Hospitals are paid based on the average national resource use for treating patients in similar circumstances, not the specific cost of treating each individual patient. With few exceptions, Medicare does not pay separately for individual items or services. Physicians and hospital staff determine the appropriate course of treatment, and hospitals receive a bundled payment for the covered inpatient facility services provided to the Medicare patient. Hospitals receive one IPPS payment per Medicare case at discharge that equates to the total Medicare payment for the facility costs of caring for that Medicare patient. More information on determining IPPS payment is located on the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Also as discussed in the CMS Innovators' Guide to Navigating Medicare,[29] the IPPS is designed to adapt to changing technology through

[28] *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf.*

[29] *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf.*

year-to-year adjustments in Medicare Severity—Diagnosis Related Groups (MS–DRG) weights based on historical cost data. In theory, if new technologies lead to better care but are more expensive, or if they lead to more efficient care and are less expensive, hospitals will eventually receive appropriate payment as the MS–DRG weights are adjusted over time to reflect the impact of fluctuating costs. In practice, however, there are concerns that the system may be slow to react to rapidly evolving technological advancements.

Hospitals may experience a financial disadvantage as they provide more expensive products and services to Medicare beneficiaries while waiting for MS–DRG payments to reflect the higher costs. Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. As an incentive for hospitals to adopt new technologies during the period before their costs are recognized in the MS–DRG weights, certain new medical services or technologies may be eligible for new technology add-on payments. The new technology add-on payment policy provides additional payments for eligible high cost cases without significantly eroding the incentives provided by a payment system based on averages. To qualify for add-on payments, the regulations at 42 CFR 412.87 generally specify a medical service or technology must be: (1) New, (2) demonstrate a SCI over existing technology, and (3) be high cost such that the MS–DRG payment that would normally be paid is inadequate. For a complete discussion on the new technology add-on payment criteria, we refer readers to the fiscal year (FY) 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Since it can take 2 to 3 years for reflection of cost data in the calculation of the MS–DRG weights, technologies generally are considered new for 2 to 3 years after they become available. Applicants must demonstrate that their product offers SCI and the other NTAP requirements.

Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed the threshold amount for the MS–DRG (or the case-weighted average of all relevant MS–DRGs, if the new technology could be assigned to many different MS–DRGs).

Although any interested party may submit an application for a new technology add-on payment, applications often come from the manufacturer of a new drug or device. Preliminary discussions on whether or not new technologies qualify for add-on payments are published in the annual IPPS proposed rules and are open to public comment.

The actual add-on payments are based on the cost to hospitals for the new technology. A new technology add-on payment is made if the total covered costs of the patient discharge exceed the MS–DRG payment of the case (including adjustments for indirect medical education (IME) and disproportionate share hospital (DSH), but excluding outlier payments). The total covered costs are calculated by applying the cost-to-charge ratio (that is used for inpatient outlier purposes) to the total covered charges of the discharge.

Under § 412.88, if the costs of the discharge exceed the full MS–DRG payment, the additional payment amount equals the lesser of the following: (1) 50 percent of the costs of the new medical service or technology; (2) or 50 percent of the amount by which the total covered costs of the case (as determined above) exceed the standard MS–DRG payment, plus any applicable outlier payments if the costs of the case exceed the MS–DRG, plus adjustments for IME and DSH. More information on IPPS new technology add-on payments, including the deadline to submit an application, is located on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

ii. SCI Criteria for the New Technology Add-On Payment Under the IPPS

Under section 1886(d)(5)(K)(vi) of the Act, a medical service or technology will be considered a ''new medical service or technology'' if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment. For a more complete discussion of the establishment of the current criteria for the new technology add-on payment, we refer readers to the IPPS final rule published on September 7, 2001 in the **Federal Register** (66 FR 46913), referred to as ''FY 2001 IPPS final rule,'' where we finalized the ''substantial improvement'' criterion to limit new technology add-on payments under the IPPS to those technologies that afford clear improvements over the use of previously available technologies. Specifically, we stated that we would evaluate a request for new technology add-on payments against the following criteria to determine if the new medical service or technology would represent a SCI over existing technologies:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. We also noted examples of outcomes that are frequently evaluated in studies of devices. For example,

++ Reduced mortality rate with use of the technology.

++ Reduced rate of technology related complications.

++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

++ Decreased number of future hospitalizations or physician visits. More rapid beneficial resolution of the disease process treatment because of the use of the device.

++ Decreased pain, bleeding, or other quantifiable symptom.

++ Reduced recovery time.

In the FY 2001 IPPS final rule (66 FR 46913), we stated that we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. We also stated that where such an improvement is not demonstrated, we continue to believe the incentives of the DRG system would provide a useful balance to the introduction of new technologies. In that regard, we also pointed out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We stated that we believe that it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.

We noted in the FY 2020 IPPS proposed rule (84 FR 19274 through 19275), that applicants for add-on payments for new medical services or technologies must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a SCI, along with a significant sample of cost data to demonstrate that the medical service or technology meets the cost criterion. Complete application information, along with final deadlines for submitting a full application, is posted on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

Per section 1886(d)(5)(K)(i) of the Act, the Secretary is required to establish a mechanism to recognize the costs of new medical services and technologies under the payment system after notice and opportunity for public comment. The payment rate updates and policy changes including new technology add-on payments under the IPPS are completed through the annual notice-and-comment rulemaking process with an October 1 effective date. In the proposed rule, CMS reviews each application and the information and clinical evidence provided by the applicant on how it meets each of the new technology add-on payment criteria. Regarding SCI, we work with our medical officers to evaluate whether a technology represents an SCI. Under the IPPS, public input before publication of a notice of proposed rulemaking on add-on payments is required by section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, and provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a SCI or advancement. In the final rule, we make a determination whether an applicant has met the new technology add-on payment criteria and is eligible for the add-on payment.

The IPPS proposed and final rules go on display around April and August, respectively, each year. The FY 2020 IPPS proposed rule is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices-Items/CMS-1716.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

b. Proposed Transitional Add-On Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

As we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38350 through 38353), following publication of the CY 2019 ESRD PPS final rule (83 FR 56969 through 56970), which discussed the comment solicitation on expanding the outlier policy to include composite rate drugs and supplies, we received additional information from dialysis equipment and supply manufacturers and a TEP meeting held in December 2018 regarding composite rate equipment and supplies. Discussions of the key findings from the TEP meeting can be found in section VIII.A of this final rule. In addition, some manufacturers have informed us that there is little incentive for them to develop innovative equipment and supplies for the treatment of ESRD primarily because ESRD facilities have no incentive to adopt innovative dialysis equipment and supplies since they are included in the ESRD PPS bundled payment and currently no additional payment is made.

In addition, we stated that we believed innovations in kidney care are likely as a result of the Kidney Innovation Accelerator (known as KidneyX). KidneyX is a public-private partnership between the Department of Health and Human Services and the American Society of Nephrology to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.

KidneyX seeks to improve the lives of dialysis patients by accelerating the development of drugs, devices, biologics and other therapies across the spectrum of kidney care including prevention, diagnostics, and treatment. KidneyX's first round of prize funding focused on accelerating the commercialization of next-generation dialysis products, aiming to reduce the risk of innovation by streamlining processes, reducing regulatory barriers, and modernizing the way we pay for treatment. More than 150 applications were reviewed, covering a full-range of innovative proposals, including advances in access, home hemodialysis and peritoneal dialysis, adjuncts to current in-center dialysis, and proposals for implantable devices, externally-worn devices and prototypes for an artificial kidney. More information regarding KidneyX is available at the following link: *http://www.kidneyx.org/.*

We stated that we believed some of the prototypes developed as part of the KidneyX will be the type of innovation the commenters requested and we want to incentivize ESRD facility use of those products. We noted that in order for equipment and supplies awarded through the KidneyX to be eligible for the additional payment the items would also need to be determined by CMS to be a renal dialysis service and meet other eligibility criteria described in section II.B.3.b.i of the CY 2020 ESRD PPS proposed rule (84 FR 38353 through 38355). We also noted that the goals for KidneyX and our proposal are different but complementary; KidneyX is focused on accelerating innovation in the prevention, diagnosis, and treatment of kidney disease, at the beginning stages of the development of an innovative product, while our proposals were intended to support uptake of new and innovative renal dialysis equipment and supplies after they have been authorized for marketing by FDA and meet other requirements, all of which happen after the development stage.

In addition, on July 10, 2019, the President signed an Executive Order [30] aimed at transforming kidney care in America. The Executive Order established many initiatives, including the launch of a public awareness campaign to prevent patients from going into kidney failure and proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease and encouraging the development of breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available.

i. Proposed Eligibility Criteria for Transitional Add-On Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies

As we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354 through 38355), in consideration of the feedback we have received, we agree that additional payment for certain renal dialysis equipment and supplies may be warranted under specific circumstances. We proposed to provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities (with the exception of capital-related assets). We proposed to call this payment adjustment the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies or TPNIES.

Renal dialysis equipment and supplies are medically necessary

[30] *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/.*

equipment and supplies used to furnish renal dialysis services in a facility or in a patient's home. We proposed that ''new'' renal dialysis equipment and supplies are those that are granted marketing authorization by FDA on or after January 1, 2020. By including FDA marketing authorizations on or after January 1, 2020, we intend to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. We solicited comment on this aspect of our proposal and whether a different FDA marketing authorization date—for example, on or after January 1, 2019—might be appropriate.

We stated in the CY 2020 ESRD PPS proposed rule that, for new and innovative equipment and supplies, we believed the IPPS SCI criteria and the process used to evaluate SCI under the IPPS can be used as a proxy for identifying new and innovative equipment and supplies worthy of additional payment under the ESRD PPS. We noted that under the IPPS, CMS has been assessing new technologies for many years to assure that the additional new technology add-on payments to hospitals are made only for truly innovative and transformative products, and we stated that CMS is proposing to adopt the IPPS SCI criteria under the ESRD PPS for the same reason. We explained that we wanted to ensure that the add-on payment adjustments made under the ESRD PPS are limited to new equipment and supplies that are truly innovative. In addition, since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we stated that we believed the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under Medicare.

Therefore, we proposed to adopt IPPS's SCI criteria specified in § 412.87(b)(1), including modifications finalized in future IPPS final rules, to determine when a new and innovative renal dialysis equipment or supply is eligible for the TPNIES under the ESRD PPS. That is, we would adopt IPPS's SCI criteria in § 412.87(b)(1) and any supporting policy around this criteria as discussed in IPPS preamble language. We stated that we believed that by incorporating the IPPS SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have standard criteria to meet for both settings. We also proposed to establish a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87(b)(1). That is, we proposed that CMS would use a similar process to determine whether the renal dialysis equipment or supply meets the eligibility criteria proposed in newly added § 413.236(b). Similar to how we evaluate whether a new renal dialysis drug or biological product is eligible for the TDAPA, as discussed in the CY 2016 ESRD PPS final rule (80 FR 69019), we would need to determine whether the renal dialysis equipment and supply meets our eligibility criteria for the TPNIES.

We noted that IPPS has additional criteria that is specific to its payment system, that is, a high cost criteria relative to the MS–DRG payment. We did not propose to adopt the specific IPPS high cost criteria requirements under § 412.87(b)(3) under the ESRD PPS since the basis of payment is different. Specifically, under the ESRD PPS, the basis of payment is the per treatment payment amount that is updated annually by the ESRD bundled market basket and the multifactor productivity (MFP) adjustment. For this reason we only proposed to adopt the SCI criteria in § 412.87(b)(1) and did not consider the high cost criteria requirements.

We proposed to exclude capital-related assets from eligibility for the TPNIES, which we would define based on the Provider Reimbursement Manual (Pub. L. 15–1) (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). The Provider Reimbursement Manual is available on the CMS website at *https://www.cms.gov/NoRegulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html*. We explained that this would include certain renal dialysis equipment and supplies. An examples of a capital-related asset for ESRD facilities could include water purification systems. We stated that we did not believe that we should provide an add-on payment adjustment for capital-related assets because the cost of these items are captured in cost reports, depreciate over time, and are generally used for multiple patients. Since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. We therefore stated that we believed capital-related assets should be excluded from the TPNIES at this time, and proposed an exclusion to the eligibility criteria in new § 413.236(b)(2). However, we noted that capital-related asset cost data from cost reports are used by CMS in regression analyses to refine the ESRD PPS so that the cost of any new capital-related assets is accounted for in the ESRD PPS payment adjustments.

Under our proposal, in addition to having marketing authorization by FDA on or after January 1, 2020, and meeting SCI criteria as determined under § 412.87(b)(1), the equipment or supply must be commercially available, have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and have been designated by CMS as a renal dialysis service under § 413.171. We proposed that following FDA marketing authorization, in order to establish a mechanism for payment, the equipment or supply would then go through a process to establish a billing code, specifically a HCPCS code. This information is necessary to conform to the requirements for both CMS and provider billing systems. Information regarding the HCPCS process is available on the CMS website at *https://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Index.html*.

Under our proposal, we would model our determination process similar to that of IPPS's NTAP. That is, manufacturers would submit all information necessary for determining that the renal dialysis equipment or supply meets the eligibility criteria listed in § 413.236(b). That would include FDA marketing authorization information, the HCPCS application information, and studies submitted as part of these two standardized processes, an approximate date of commercial availability, and any information necessary for SCI criteria evaluation. For example, clinical trials, peer reviewed journal articles, study results, meta-analyses, systematic literature reviews, and any other appropriate information sources can be considered.

We proposed to provide a description of the equipment or supply and pertinent facts related to it that can be evaluated through notice-and-comment rulemaking. We stated that we would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in newly added § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In order to implement the TPNIES for a particular calendar year, we would only consider a complete application received by CMS by February 1 prior to the particular calendar year.

For example, under our proposal, in order to receive the TPNIES under the

ESRD PPS effective January 1, 2022 we would require that a complete application meeting our requirements be received by CMS no later than February 1, 2021. Then, we would include a discussion of the renal dialysis equipment or supply requesting the TPNIES in the CY 2022 ESRD PPS proposed rule. Our evaluation of the eligibility criteria would be addressed in the CY 2022 ESRD PPS final rule. If the renal dialysis equipment or supply qualifies for the TPNIES, payment would begin January 1, 2022.

Alternatively, we considered an application deadline of September 1, however, we proposed an earlier timeframe so that the TPNIES would be implemented sooner. We noted that a September 1 deadline would provide more time initially for manufacturers to submit applications. We solicited comment on the proposed deadline date for the application.

To codify the requirements for the TPNIES, including the eligibility, we proposed to add § 413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies. We proposed to add § 413.236(a) to state that the basis for the section is to establish a payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD PPS under the authority of section 1881(b)(14)(D)(iv) of the Act.

We proposed to add § 413.236(b) to address the eligibility requirements for the TPNIES. Under the proposed paragraph (b), for dates of service occurring on or after January 1, 2020, we would provide a TPNIES as specified in paragraph (d) that is added to the per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics as described in §§ 413.232 and 413.235 to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available, (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures, (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) and related guidance, and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

We also proposed to add § 413.236(c) to establish a process for the TPNIES eligibility determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. That is, we proposed that we would consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. We proposed that we would only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the TPNIES would take effect.

We solicited comment on the proposed criteria to determine new and innovative renal dialysis equipment and supplies that would be eligible for TPNIES. In addition, we solicited comment on the use of different evaluative criteria and, where applicable, payment methodologies, for renal dialysis supplies and equipment that may be eligible for the TPNIES under the ESRD PPS. These criteria could include cost thresholds for high cost items. We solicited comment on whether any of the IPPS SCI criteria would not be appropriate for the ESRD facility setting and whether there should be additional criteria specific to ESRD. We sought comment on whether to use FDA's pre-market authorization and De Novo pathways as a proxy for or in place of the proposed SCI criteria. In addition, we solicited comment on potential implementation challenges, such as what sources of data that CMS should utilize to assess SCI and the proposed process that would be used to determine SCI. Finally, we solicited comment on the benefits and drawbacks of the proposed SCI criteria.

The comments and our responses to the comments on our proposals regarding eligibility criteria for the TPNIES are set forth below.

Comment: All of the comments we received supported the establishment of the TPNIES to spur innovation for new renal dialysis equipment and supplies. Several commenters expressed support for the proposed TPNIES definition of ''new'' and ''innovative'' as a device granted FDA marketing authorization that demonstrates SCI using criteria similar to those applied under the IPPS NTAP. MedPAC and an LDO also expressed support for the process outlined in the CY 2020 ESRD PPS proposed rule. MedPAC expressed support for transparent and predictable processes with established routines for the agency, stakeholders, and the public. MedPAC pointed out that the proposed annual process of review for TPNIES eligibility provides manufacturers a forum for feedback and questions, and it provides other stakeholders with opportunities to participate in the process.

Response: We appreciate the commenters' support.

Comment: A physician association stated that it is critical to support innovation in kidney care, but stressed that there must also be a specific focus on innovations that also pertain to the pediatric space. New products and therapies that come to market are not always tested in the pediatric population or are even appropriate for children, and. policies must be put in place to change this moving forward. The association emphasized that children and adolescents are not simply ''little adults.'' Rather, they have a unique physiology characterized by maturing organ function, body metabolism, and body distribution characteristics distinct from what adults manifest. Due to these differences, the safety and efficacy data of equipment and supplies developed for adults and only studied in adults may not be appropriate for pediatric patients. The association acknowledged that the small number of pediatric patients complicates conducting safety, efficacy, or interventional trials in children, but stated that the importance of this data is crucial to allow children to also benefit from innovation.

Response: We hope that by providing the TPNIES, equipment and supply manufacturers will develop new and innovative renal dialysis products for pediatric patients as well as adult patients and that the clinical trials conducted for such products include pediatric patients. By establishing the TPNIES for new and innovative renal dialysis equipment and supplies, we believe that manufacturers will be encouraged to develop new products, including new and innovative products for pediatric patients. We note that our data analysis contractor will be holding a TEP meeting in December 2019 and intends to address the topic of pediatric dialysis.

Comment: Most stakeholders expressed concern that the TPNIES proposal excludes capital-related assets. A national dialysis stakeholder organization and an LDO requested that CMS propose in the next rulemaking a pathway for accounting for new capital equipment in the ESRD PPS. The organization pointed out that the IPPS NTAP payment for new devices does not address capital equipment because those costs are incorporated in the base rates using other mechanisms linked to

the cost reports. As there is no similar mechanism under the ESRD PPS, the organization asked that CMS propose in the CY 2021 ESRD PPS proposed rule a mechanism that would adjust the ESRD PPS base rate to account for the cost of innovative renal dialysis capital equipment as well. The organization stated that this policy is important because many innovative devices, including some that the President has highlighted, would be capital equipment. A device manufacturer also recommended that we propose to include purchased capital equipment in the CY 2021 ESRD PPS proposed rule.

An LDO stated that the proposed eligibility for the TPNIES is overly narrow, and does not address the need and potential for achieving innovations in the most central component of dialysis care. A professional association agreed, noting that significant innovation and technology improvement is occurring in the area of dialysis machines and peritoneal dialysis cyclers and that innovation in the efficiency and effectiveness of water systems would both improve patient quality of care, as well as reduce costs for facilities and help to preserve the nation's water supply.

Another LDO also recommended that CMS eliminate the exclusion for capital-related assets from the TPNIES criteria. The LDO noted it is sensitive to the operational challenges highlighted by CMS that would emerge if capital-related assets were eligible for the TPNIES. The LDO expressed appreciation for CMS' desire to arrive at a policy that is operationally simple but maintained that the challenges cited by CMS in applying the TPNIES to capital-related assets can be overcome. Alternatively, the LDO recommended that CMS consider a separate add-on payment methodology to capture the costs of capital-related assets under its existing authority to include other payment adjustments in the ESRD PPS as the Secretary determines appropriate.

MedPAC stated that the proposal is unclear about whether capital-related assets that are leased are excluded from eligibility for the TPNIES. MedPAC pointed out that in the proposed rule, the definition of a capital-related asset refers to the Provider Reimbursement Manual (Chapter 1, Section 104.1), which does not distinguish between capital-related items that are purchased versus those that are leased. MedPAC requested that we clarify in the CY 2020 ESRD PPS final rule whether a capital-related asset that is leased would be eligible for the TPNIES.

A health services company recommended that CMS clarify that equipment or supplies used for home dialysis are not subject to the ''capital-related asset'' criteria and confirm that a leased home dialysis device would not be a capital-related asset. The company stated that our proposal uses the hospital cost reporting definition of a depreciable asset, which it strongly believes should not apply in the case of home dialysis equipment or supplies that are not used by multiple patients in a facility but rather are used exclusively by a single patient in the patient's home. The company indicated that this change to the eligibility criteria would help better align the TPNIES with the Administration's bold goals for moving kidney care away from its current reliance on in-center dialysis to more availability and use of home dialysis. A device manufacturer stated that including leased capital equipment is feasible under the currently proposed payment approach, leveraging existing coding mechanisms and the proposed invoice-based payment process.

An LDO acknowledged that the cost report design may make it difficult to differentiate capital-related assets on a per treatment basis and that is why CMS proposed to exclude capital-related assets. However, the LDO stated that in doing so, in effect, CMS is only creating a payment adjustment for renal dialysis supplies. Until the work can be accomplished to differentiate capital related assets on cost reports, the commenter suggested that CMS only exclude capital-related assets generally used for multiple patients. The commenter stated that by allowing single patient use equipment, CMS would be fostering more patient-engaged solutions like those found in the Kidney X prize competition and for home modalities.

A patient advocacy organization stated that while it appreciates the complexity involved in establishing a payment adjustment for capital-related assets on a per-treatment basis, the organization believes it is critically important to implement incentives that may result in lighter and easier to use home dialysis machines, especially given the Administration's efforts to increase the uptake of home dialysis. The organization stated that home dialysis machines are both leased and purchased by facilities, so it believes both types of machines should ultimately be eligible for the TPNIES, though it supports CMS' efforts to begin with considering leased equipment for eligibility.

Response: As we stated in the CY 2020 ESRD PPS proposed rule, we do not believe that we should provide the TPNIES for capital-related assets because the cost of these items is captured in cost reports, depreciate over time, and are generally used for multiple patients. Additionally, since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. Therefore, we proposed to exclude capital-related assets from eligibility for the TPNIES in new § 413.236(b)(6). Further, we believe providing the TPNIES for capital-related assets is complex given the various leasing arrangements and depreciation.

While we acknowledge that significant innovation and technology improvement is occurring with dialysis machines and peritoneal dialysis cyclers, as well as innovation in the efficiency and effectiveness of water systems, at this time we do not have enough information regarding current usage of the various financial and leasing arrangements, such as those involving capital-leases for depreciable assets versus operating leases recorded as operating expenses. In addition, methodological issues regarding depreciation need to be assessed in order to determine whether TPNIES eligibility for these items would be appropriate. We need to further study the specifics of the various business arrangements for equipment related to renal dialysis services. This would include items that are: (1) Purchased in their entirety and owned as capital-related assets; (2) assets that are acquired through a capital-lease arrangement; (3) equipment obtained through a finance lease and recorded as an asset per the Financial Accounting Standards Board (FASB) guidance on leases (Topic 842) effective for fiscal years beginning after December 15, 2018,[31] or (4) equipment obtained through an operating lease and recorded as an operating expense. In addition to the variety of business arrangements, there are unknown issues relating to ownership of the item and who retains title, which flows into the equipment's maintenance expenses for capital-related assets. Further, there is the question of the definition of single use versus multiple use for equipment used for renal dialysis services. For example, capital-related assets used in-center and in the home may be used by multiple patients over their useful lifetime. Specifically, equipment classified as capital-related assets may be refurbished and used by another patient. At this

[31] FASB Accounting Standards Update: No. 2016–02, February 2016; Leases (Topic 842); An Amendment of the FASB Accounting Standards Codification. *https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=1176167901010&acceptedDisclaimer=true.*

time, we are unable to adequately assess the eligibility of these items for the TPNIES. We intend to gather additional information about how ESRD facilities obtain their capital-related equipment in future meetings with the TEP.

With regard to capital-lease equipment for home dialysis, we note that historically we have always supported patient choice with regard to dialysis modality and we support the Administration's initiatives for home dialysis. However, we did not intend for capital-lease assets to be eligible for the TPNIES at this time. We note that regulations at § 413.130(b)(1) ''Introduction to capital-related costs,'' specifies that leases and rentals are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. In the future, we will be closely examining the treatment of capital-related assets under Medicare, including our regulations at § 412.302 regarding capital costs in inpatient hospitals and § 413.130, as they relate to accounting for capital-related assets, including capital-lease and the newly implemented guidance for finance lease arrangements, to determine if similar policies would be appropriate under the ESRD PPS.

Comment: A device manufacturers' association pointed out that since most medical equipment is purchased as a capital-related asset, the TPNIES effectively would exclude the innovative equipment identified in the title of the adjustment. The association noted that meaningful clinical improvements and patient experience improvements are arguably more likely to come from innovation outside single-use supplies. The association stated that expanding the TPNIES to include medical equipment, regardless of how it is purchased by the provider, would stimulate greater investment in a broader array of new technologies for ESRD patients.

Response: We recognize that accounting for renal dialysis service equipment can vary depending on the individual ESRD facility's business model. For example, when the owner of the capital-related asset retains title, then the renal dialysis service equipment is a depreciable asset and depreciation expense could be itemized. When there is no ownership of the renal dialysis service equipment, then the item is recorded as an operating expense. We disagree with the commenter and believe that there could be new and innovative equipment that are not capital-related assets and could therefore be eligible for the TPNIES. For example, there could be a supply or piece of equipment that is purchased outright by the ESRD facility that may be able to withstand repeated use over the treatment month and lasts less than a year, that does not fall under the definition of capital-related asset in § 413.236(b)(6).

Comment: A device manufacturer recommended that CMS change the definition of the TPNIES from new and innovative equipment and supplies to new and innovative equipment, supplies, and services. The manufacturer stated that this modification would align the ESRD PPS TPNIES definition with the IPPS NTAP and would clarify that the TPNIES would apply not only to new technologies, but also to new services that meet the SCI requirements. In addition to aligning the TPNIES definition with that of the IPPS NTAP, the manufacturer noted, this modification would clarify that non-technology services that benefit ESRD patients can also qualify for the TPNIES if they meet the SCI criteria. The manufacturer stated that this is important because innovations to address care of ESRD patients are not limited solely to new technology. For example, novel home dialysis educational programs or remote monitoring services could create real benefit for ESRD beneficiaries, but would not necessarily be defined as technologies.

Response: Our proposal was limited to renal dialysis supplies and equipment that receive FDA marketing authorization, so we are unable to adopt this recommendation to include services in the definition of TPNIES for CY 2020.

Comment: A national dialysis stakeholder organization, a national dialysis association, an LDO and other commenters asked that CMS shift the application deadline for the TPNIES to later in the year. They expressed concern that the February 1 deadline may be difficult to meet, but the September deadline might not provide enough time for CMS to apply the TPNIES in the next calendar year.

Many commenters recommended that CMS adopt timelines that provide maximum flexibility to manufacturers in meeting the application deadline, particularly in the first year of the program and asked that CMS extend the February 1, 2020 application deadline to April or May. They stated that manufacturers would benefit from additional time in the first year of the program because the process will be new and manufacturers were not able to prepare for it during development of their products. More importantly, several commenters urged CMS to allow manufacturers to file applications for products that are expected to receive FDA authorization for marketing before the next calendar year, but not require that marketing authorization take place prior to the application deadline. The commenter pointed out that this approach is allowed for the NTAP application, which requires only that a product is pending marketing authorization at the FDA at the time of filing the NTAP application.

Response: The commenters are correct that finalizing a September 1 deadline for submission of an application for the TPNIES would delay payment of the TPNIES for an entire year. In order to obtain public comment on the TPNIES application through the ESRD PPS rulemaking process, we would need to receive a complete application with sufficient information to include in the annual ESRD PPS proposed rule by February 1. We agree that a February 1 deadline, particularly for CY 2020, may not provide sufficient time for manufacturers with products in FDA review to meet the new requirements of § 413.236(c). However, our goal is to support uptake of new and innovative equipment and supplies for those manufacturers that are ready to supply ESRD facilities with these innovative products. Therefore, for CY 2020 we are finalizing the February 1 application deadline because we want to provide the opportunity for expedited payment of the TPNIES. We note that otherwise ESRD facilities would not receive the TPNIES for any equipment and supplies in CY 2021. We are clarifying that submissions to FDA for marketing authorization must have been submitted to FDA by the time the TPNIES application is submitted to CMS, that is, February 1. The FDA marketing authorization need not occur until September 1 of the same year so that we are able to finalize the TPNIES in the annual ESRD PPS final rule. We are revising § 413.236(c) to clarify that FDA marketing authorization must occur by September 1 in order for the product to be eligible for the TPNIES on January 1 of the following year. More information regarding TPNIES application submissions in CY 2020 is discussed later in this section.

Comment: As explained previously, we proposed to define new renal dialysis equipment and supplies as those that are granted marketing authorization by FDA on or after January 1, 2020. However, we solicited comment on whether a different FDA marketing authorization date, for example, on or after January 1, 2019, might be appropriate. Many commenters, including a device

manufacturers association, a device manufacturer, a medical technology company, a national dialysis stakeholder organization, a national dialysis association, an LDO, and a home dialysis association expressed support for a January 1, 2019 FDA marketing authorization date.

One of the commenters suggested that CMS eliminate the newness criterion. The commenter stated that while little innovation has occurred in ESRD in decades, there are a limited number of products developed that have been unsuccessful in entering the market because of reimbursement barriers. The commenter asserted that the proposed January 1, 2020 date would encourage use of technologies that are currently in development, but have not yet entered the market, putting earlier innovators at a disadvantage. The commenter maintained that the same incentive for use should be applied to technologies that have recently gained approval and have had limited market uptake, in many cases because they are more costly than existing technologies, despite presenting substantial clinical improvement.

A software development company stated that it is important that CMS implement the TPNIES in a manner that maintains a level playing field. In other words, CMS must work collaboratively with FDA to ensure all new market entrants undergo the appropriate regulatory oversight prior to marketing their equipment and supplies. The company stated that CMS must also implement the TPNIES in a manner that avoids rewarding technology vendors for achieving overdue FDA marketing authorization. Further, technologies that have already completed the regulatory oversight process should be able to access the same incentives, that is, the new add-on payment adjustment.

The company encouraged CMS to ensure the eligibility of technologies that have already obtained FDA marketing authorization, and are not reimbursed under the ESRD PPS, for the TPNIES. This approach would assist CMS in achieving greater competition and innovation, as opposed to making eligible just those products granted marketing authorization by the FDA on or after January 1, 2020, as envisioned by the proposed rule.

Another commenter expressed similar concerns and recommended that CMS extend eligibility for the TPNIES to products receiving marketing authorization on or after January 1, 2019, and even consider on or after January 1, 2018 as the criterion. The commenter stated that this would allow a technology to be eligible for the TPNIES if it recently received marketing authorization but has struggled with market adoption because of financial disincentives in the ESRD PPS.

Another commenter recommended that CMS extend the eligibility for the TPNIES back to a January 1, 2018 FDA marketing authorization date. This would give new devices (and drugs) that may be eligible to participate in IPPS' NTAP or OPPS' pass-through, a 2-year window from the regulatory date of approval, or when the product is introduced to market, to participate in the respective programs. The commenter also noted that there have been highly innovative products, which could significantly benefit the Medicare population, which have been approved over the last 2 years. The commenter stated there are a limited number of recently approved highly innovative products for the ESRD patient population and encouraged CMS to grant as much flexibility as possible related to the FDA marketing authorization date.

However, a non-profit provider association stated that a prospective, rather than retrospective, date is appropriate, since part of the basis for providing additional payment is to spur innovation, which industry stakeholders have said has been thwarted.

Response: After careful consideration of these comments, we have decided to finalize the proposed definition of new to mean granted marketing authorization by FDA on or after January 1, 2020. While we appreciate that manufacturers of renal dialysis equipment and supplies that were granted FDA marketing authorization in prior years would want these products to be eligible for the TPNIES, our goal is not to provide a payment adjustment for all the products that have received FDA marketing authorization or for products that have had limited market uptake, but rather to establish an add-on payment adjustment for certain new and innovative products in order to support uptake by ESRD facilities of new and innovative renal dialysis equipment and supplies. In addition, we appreciate the complex issues the commenters raised if we were to select an earlier FDA marketing authorization date, and believe our approach will avoid the need to address those issues. We note that the ESRD PPS is a prospective payment system, in which changes are generally made prospectively, including eligibility requirements for add-on payment adjustments. In addition, this marketing authorization date of January 1, 2020 or later is consistent with the TDAPA's definition of a new renal dialysis drug or biological product.

Comment: Many commenters recommended that all FDA marketing authorizations under the PMA, De Novo, and 510(k) products that represent SCI should be eligible to receive the TPNIES. Given the shortage of new and innovative technologies in this disease area and the many differences between dialysis care and acute hospital services that often receive NTAP payment, they recommended that CMS consider deeming FDA's marketing authorization under the PMA or De Novo pathways as a criterion that would meet the SCI requirement. Additionally, they recommended adding a policy that would allow all approved and cleared FDA Breakthrough Therapy Designation products to meet the criteria.

A device manufacturers association and a device manufacturer and others made a similar recommendation based on their concern that the requirement that all products undergo the SCI determination process will delay patient access to needed therapies. They pointed out that products that receive FDA marketing authorization under the PMA or De Novo pathways must undergo more stringent regulatory review and provide FDA with more data than a 510(k) submission and have demonstrated a level of clinical effectiveness and newness that products cleared under the 510(k) process have not.

They believe that this policy modification would have a negligible effect on the cost of the TPNIES program to the Federal Government, but it would have a tremendous effect on encouraging innovation. The commenters pointed out that no new devices for use in an ESRD facility were authorized by the FDA under a PMA or De Novo application from 2013 to 2017.

A medical technology company agreed, recommending that we allow devices, including capital equipment, that have made significant improvements upon an existing approved device be eligible for the TPNIES when delivering product updates that meet SCI or patient preference criteria. The company stated that this approach would encourage significant innovation that is achievable in a relatively short time period, reaching today's patients.

However, MedPAC stated that CMS should not use FDA's marketing authorization processes, including PMA and De Novo pathways, as a proxy for or in place of the proposed SCI criteria. They maintain that the Medicare program, not the FDA, should adjudicate spending determinations

based on the specific needs of the Medicare population. MedPAC stated that FDA's role in the drug and device development process as a regulator is distinct and separate from the role of CMS as a payer. MedPAC noted that FDA regulates whether a device or pharmaceutical is ''safe and effective'' for its intended use by consumers. The FDA marketing authorization process may or may not include the new device or pharmaceutical's safety or effectiveness with regard to the Medicare population.

MedPAC also pointed out that there have been many examples where devices approved through expedited FDA marketing authorization have not resulted in improvements in care relative to existing technologies, and in fact many have been recalled.

Response: In the CY 2020 ESRD PPS proposed rule, we referenced the SCI criteria in § 412.87(b)(1) and did not propose the alternative pathway described in § 412.87(c) which includes devices that have FDA marketing authorization and are part of FDA's Breakthrough Devices Program (which can include De Novo and PMA) that is deemed to meet the conditions specified in § 412.87(b)(1), that is, the SCI criterion. For this reason, we are unable to adopt this change in this final rule. In addition, we believe that instead of limiting eligibility for the TPNIES to PMA and De Novo as several commenters suggested, the SCI policy will provide an opportunity for a product that has no predicate product, that is, is not the first of its kind but offers SCI, to receive the TPNIES. Additionally, with regard to the comment regarding SCI delaying patient access to therapies, we believe that this is balanced with our opportunity to review more applications for TPNIES eligibility which may lead to more treatment choice for patients.

Comment: A device manufacturers association and 2 device manufacturers stated that CMS should finalize the proposal to adopt the IPPS SCI criteria specified including modifications finalized in future IPPS rules. They pointed out that on August 2, 2019, in the FY 2020 IPPS final rule, CMS finalized changes to the SCI criteria so that manufacturers can now present a wider variety of information to support the NTAP application. These changes were made to introduce greater flexibility in the SCI decision making process. Although they believe that adoption by reference is implied, they recommended that CMS explicitly adopt the new SCI criteria in the final rule and, ultimately, in the TPNIES application itself.

Response: We acknowledge that revised criteria for assessing SCI was published in the FY 2020 IPPS final rule (84 FR 42180 through 42181). In accordance with the proposed reference to § 412.87(b)(1), which we are finalizing in new § 413.236(b)(5), we have adopted the FY 2020 IPPS changes to the SCI criteria, and any future changes to the SCI criteria, by reference, unless and until we make any changes to the criteria through notice and comment rulemaking.

Specifically, CMS will use the following criteria to evaluate SCI for purposes of the TPNIES under the ESRD PPS (see § 412.87(b)(1) and § 413.236(b)), based on the IPPS SCI criteria and related guidance:

A new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, and most importantly, the totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the U.S. or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

Comment: An LDO recommended that CMS finalize its proposal to adopt SCI as an eligibility criteria for the TPNIES, clarify and provide further guidance on how it intends to apply the new criteria, and establish a process that includes at least one reviewer of TPNIES applications with clinical expertise in ESRD care.

Response: We intend to establish a workgroup of CMS medical and other staff to review the studies and papers submitted as part of the TPNIES application, the public comments we receive, and the FDA marketing authorization and HCPCS application information and assess the extent to which the product provides SCI over current technologies. Our intent is to

obtain input from a nephrologist along with other subject matter experts throughout our decision making process for determining TPNIES eligibility.

Comment: Several commenters, including a patient advocacy organization, a medical technology company, and a medical technology association requested that CMS expand on the SCI criteria for the TPNIES to include patient preference data, and clarify at least some of the elements that would be considered as improved quality of life. The commenters noted that the Kidney Health Initiative Renal Replacement Therapy Roadmap outlines the elements that should constitute improved quality of life for patients and they believe CMS should include and apply these elements in the CY 2020 ESRD PPS final rule. They also recommended that patient preference data should be considered for evaluating SCI. They stated that it is critically important for TPNIES approvals to reflect the preferences of ESRD patients and empower their choice to do home dialysis or self-care. The organization offered to work with CMS to define a process for evaluating improvements in one or more activities of daily living and improved quality of life. The organization stated that such a process is especially important because patient preference and patient reported outcome data are not always available at the time that marketing authorization is granted by FDA. They want to ensure that equipment or supplies that represent a meaningful advance for ESRD patients, but where the patient's preferences have not yet been formally evaluated at the time of FDA marketing authorization, would be eligible for TPNIES.

Response: As stated in section II.B.1.a of the CY 2020 ESRD PPS proposed rule (84 FR 38354), since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we believe the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under the ESRD PPS. We intend to study in the future how patient preference information could be used to inform SCI determinations under the ESRD PPS to determine if we should establish any criteria that are specific to the ESRD PPS. In the interim, since TPNIES applications will be described in the annual ESRD PPS proposed rules, we urge ESRD patients and patient advocacy organizations to provide the patient perspective on the TPNIES applications in comments on the proposed rule. We note that the CMS determinations on the TPNIES applications will be issued in the annual ESRD PPS final rules based on the totality of the information provided, including public comments receiving during the rulemaking process.

Comment: A health services company pointed out that CMS did not provide a definition for commercially available and asked that we eliminate the requirement in the final rule. The company pointed out that neither the IPPS add-on payment nor OPPS pass through payment rules require that the equipment or supply be commercially available and the CY 2020 ESRD PPS proposed rule provided no rationale for including this eligibility requirement.

Response: We included the eligibility requirement that a new and innovative renal dialysis equipment or supply be commercially available for the reasons set forth below, not to be consistent with the IPPS NTAP or OPPS pass-through payment. Regarding the request that we define commercially available, we are clarifying that commercially available means available for sale to ensure that manufacturing or other delays do not significantly delay patient access to the new equipment or supply.

We expect that if an application for the TPNIES is submitted by February 1, 2020 for the equipment or supply, the equipment or supply would be available to be sold by January 1, 2021, when the TPNIES period begins, if we determine the item is eligible. In addition, we note that the TPNIES period for a product begins on January 1 and ends 2 years later on December 31. We would expect that manufacturers would want to capitalize on the marketing opportunity available during the TPNIES period and ensure that the equipment or supply is commercially available on January 1. We are concerned that if the equipment or supply is not commercially available on January 1, there may be confusion from ESRD facilities over when the TPNIES period starts and ends. Therefore, we believe this is an important criteria for eligibility for the TPNIES. If the equipment or supply is not commercially available on January 1, the manufacturer would not meet one of the eligibility criteria for TPNIES and no TPNIES payments should be made. For this reason, we expect for the manufacturer to notify CMS by September 1 if the equipment or supply will not be commercially available by January 1. If the manufacturer is unable to have market availability by January 1, 2021, the equipment or supply is not eligible for TPNIES in CY 2021.

Final Rule Action: After consideration of public comments, for CY 2020 we are finalizing the addition of § 413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies, with 5 modifications. First, we are clarifying that applicants must receive FDA marketing authorization by September 1 and not February 1; second, we are clarifying what commercially available means and when it needs to occur; third, we are clarifying when the HCPCS application needs to be submitted; fourth, we are clarifying what particular calendar year means; and fifth; we are taking out the reference to the application of the TPNIES in the calculation of the per treatment payment amount because we do not believe it is necessary in light of our changes to § 413.230. We are finalizing the addition of § 413.236(a) to state that the basis for the TPNIES is to establish an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD PPS under the authority of section 1881(b)(14)(D)(iv) of the Act.

We also are finalizing the addition of § 413.236(b) to state that a renal dialysis equipment or supply meet the following eligibility criteria in order to receive the TPNIES: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) and related guidance, and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

We are also finalizing the addition of § 413.236(c) to establish a process for the TPNIES determination and deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. That is, we are finalizing that we will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. We are finalizing that we will only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the payment adjustment would

take effect, and that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year.

ii. Pricing of New and Innovative Renal Dialysis Equipment and Supplies

In the CY 2020 ESRD PPS proposed rule (84 FR 38355), we stated that, with respect to the new and innovative renal dialysis equipment and supplies, we were not aware of pricing compendia currently available to price these items for the transitional add-on payment adjustment proposal discussed in this section. We also noted that, unlike new renal dialysis drugs and biological products eligible for the TDAPA, ASP and WAC pricing do not exist for renal dialysis equipment and supplies. Unlike the IPPS NTAP methodology, which uses MS–DRG payment and cost-to-charge ratios in its high cost criteria payment calculation, the ESRD PPS has a single per treatment payment amount. Therefore, we proposed to establish a pricing method in the absence of data indicating a true market price.

In accordance with ESRD billing instructions of the Medicare Claims Processing Manual (chapter 8, section 50.3), we proposed that ESRD facilities would report the HCPCS code, when available, and their corresponding charge for the item. We explained that, in accordance with the Provider Reimbursement Manual (chapter 22, section 2203), Medicare does not dictate a provider's charge structure or how it itemizes charges but it does determine whether charges are acceptable for Medicare purposes. Charges should be reasonably and consistently related to the cost of services to which they apply and are uniformly applied. In addition, the Provider Reimbursement Manual (chapter 22, section 2202.4) specifies that charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients' charges used in the development of apportionment ratios should be recorded at the gross value; that is, charges before the application of allowances and discounts deductions.

Since we require charges to be reported at the gross value, we did not propose to use charges as the basis of payment. The ESRD PPS does not have a charge structure or a gap-filling policy similar to the DMEPOS policy. As a result, we proposed to obtain a pricing indicator that requires the item to be priced by Medicare Administrative Contractors (MACs). We proposed to adopt a process that utilizes invoiced-based pricing. We noted that there are instances in which invoice pricing is also used for DMEPOS. Specifically, in the Medicare Claims Processing Manual (chapter 23, section 60.3), we state that ''potential appropriate sources for such commercial pricing information can . . . include verifiable information from supplier invoices.''

In addition, we noted that in the CY 2019 Physician Fee Schedule final rule (83 FR 59663), we discussed that invoice based pricing is used to pay for Part B drugs and biologicals in certain circumstances as described in the Medicare Claims Processing Manual (chapter 17, section 20.1.3). For example, if a payment allowance limit for a drug or biological is not included in the quarterly ASP Drug Pricing File or Not Otherwise Classified Pricing File, MACs are permitted to use invoice pricing. MACs may also use invoice based pricing for new drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified Pricing File. The new drug provision may be applied during the period just after a drug is marketed, that is, before ASP data has been reported to CMS. We stated that we believed using invoices for new drugs and drugs without national pricing is a similar situation to addressing new and innovative renal dialysis equipment and supplies that do not have a national price.

We stated that we believed that an invoice-based approach could be applied to the renal dialysis equipment and supplies that are the focus of our proposal. As noted previously, ESRD facility charges are gross values; that is, charges before the application of allowances and discounts deductions. We stated that we believed the MAC-determined price should reflect the discounts, rebates and other allowances the ESRD facility (or parent company) receives. These terms are defined in the Provider Reimbursement Manual (chapter 8).[32] If the MAC-determined price does not reflect discounts, rebates and other allowances, the price would likely exceed the facility's cost for the item and result in higher co-insurance obligations for beneficiaries. For this reason, we noted that it is important for MACs to develop a payment rate taking into consideration the invoice amount, the facility's charge for the item on the claim, discounts, allowances, rebates, the price established for the item by other MACs and the sources of information used to establish that price, payment amounts from other payers and the information used to establish those payment amounts, and information on pricing for similar items used to develop a payment rate. We explained that we believe the information that ESRD facilities would supply to the MACs should be verifiable, so that we can more appropriately establish the actual facility cost of the items.

Under our proposal, the specific amounts would be established for the new and innovative renal dialysis equipment or supply HCPCS code using verifiable information from the following sources of information, if available: The invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We stated that once there is sufficient payment data across MACs, we would consider establishing a national price for the item through notice and comment rulemaking. We invited public comment on this proposed approach for pricing new and innovative renal dialysis equipment and supplies for the transitional add-on payment adjustment proposal discussed in section II.B.3.b.iii of this final rule. We also solicited comment on other pricing criteria and other verifiable sources of information that should be considered.

To mitigate the Medicare expenditures incurred as a result of the TPNIES proposal discussed later in this section of the final rule, we proposed to base the additional payment on 65 percent of the MAC-determined price. We noted that in the FY 2020 IPPS proposed rule (84 FR 19162) a 50 percent capped add-on amount was considered low with regard to providing hospitals with a sufficient incentive to use the new technology. In that rule, we proposed to modify the current payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent. In the FY 2020 IPPS final rule (84 FR 42048), the percentage was revised to be 65 percent. In the CY 2020 ESRD PPS proposed rule (84 FR 38356), we stated we believed that we have the same goal as IPPS with regard to supporting ESRD facility use of new and innovative renal dialysis equipment and supplies. Therefore, we proposed to base the TPNIES on 65 percent of the

[32] Medicare Provider Reimbursement Manual. Chapter 8. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R450PR1.pdf.*

MAC-determined price. We also solicited comment on whether we should explicitly link to the IPPS NTAP mechanism's maximum add-on payment amount percentage so that any change in that percentage would also change for the proposed TPNIES paid to ESRD facilities for furnishing new and innovative renal dialysis equipment and supplies.

iii. Proposed Use of a Transitional Add-On Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies

In the CY 2020 ESRD PPS proposed rule, we acknowledged that ESRD facilities have unique challenges with regard to implementing new renal dialysis drugs and biological products as discussed in section II.B.1.b of this final rule, and we stated that we believed that the same issues would apply with respect to incorporating new and innovative equipment and supplies into their standards of care. For example, when new and innovative equipment and supplies are introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a product and its effect on patient outcomes. We stated that we believed this uptake period would be supported by the proposed TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS. The proposed TPNIES would target payment for the use of new and innovative renal dialysis equipment and supplies during the period when a product is new to the market.

We proposed to apply the TPNIES for 2-calendar years from the effective date of the change request, which would coincide with the effective date of the CY ESRD PPS final rule. We also proposed that after the TPNIES period ends, the item would become an eligible outlier service as provided in § 413.237. Therefore, we proposed revisions to § 413.237(a)(1) to reflect outlier eligibility for the new renal dialysis equipment or supply once the TPNIES period ends. We stated that we believed that 2 years would be a sufficient timeframe for ESRD facilities to set up or adjust business practices so that there is seamless access to the new and innovative equipment and supplies. In addition, historically when we have implemented policy changes whereby facilities need to adjust their system modifications or protocols, we have provided a transition period. We noted that we believed that this 2-year timeframe is similar in that facilities are making changes to their systems and care plans to incorporate the new renal dialysis equipment and supplies into their standards of care and this could be supported by a transition period.

Further, we stated that we believed providing the TPNIES for 2 years would address the stakeholders' concerns regarding additional payment to account for higher cost of more new and innovative equipment and supplies that they believe may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, the TPNIES would give the new and innovative equipment and supplies a foothold in the market so that when the timeframe is complete, they are able to compete with the other equipment and supplies also accounted for in the ESRD PPS base rate. Once the 2-year timeframe is complete, we proposed that the equipment or supply would then qualify as an outlier service, if applicable, and the facility would no longer receive the TPNIES for that particular item. Instead, in the outlier policy space, there is a level playing field where products could gain market share by offering the best practicable combination of price and quality.

We noted that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary co-insurance, since we have not previously provided a payment adjustment for renal dialysis equipment and supplies in the past. However, to support agency initiatives and to be consistent with both our TDAPA policy and IPPS payment policies, we noted that we believed that the proposed TPNIES would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment and supplies.

We stated that the intent of the TPNIES would be to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative equipment and supplies. We explained that, at this time, we do not believe that it would be appropriate to add dollars to the ESRD PPS base rate for new and innovative renal dialysis equipment and supplies because, as noted previously, the ESRD PPS base rate includes the cost of equipment and supplies used to furnish a dialysis treatment. As we have stated in CY 2019 ESRD PPS proposed rule (83 FR 34314), we believe that increasing the base rate for these items could be in conflict with the fundamentals of a PPS. That is, under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average cost and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's resource use which creates an incentive for facilities to control their costs. It is not the intent of a PPS to add dollars to the base rate whenever a new product is made available.

Therefore, we also proposed to add § 413.236(d) to provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment or supply based on 65 percent of the MAC-determined price, as described in proposed § 413.236(e). The TPNIES would be paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate would not be modified and the new and innovative renal dialysis equipment or supply would be an eligible outlier service as provided in § 413.237.

We also proposed to add § 413.236(e) to require that the MAC on behalf of CMS would establish prices for the new and innovative renal dialysis equipment and supplies described in newly added § 413.236(b), and that we would use these prices for the purposes of determining the TPNIES. The specific amounts would be established for the new and innovative renal dialysis equipment or supply HCPCS code using verifiable information from the following sources of information, if available: The invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We also proposed to add paragraph (e) to § 413.230, Determining the per treatment payment amount, to reflect the TPNIES. We stated that we believed this modification is necessary so the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount.

Since we were proposing to add paragraphs (d) (discussed in section II.B.1.e of this final rule) and (e) to § 413.230, we also proposed a technical change to remove ''and'' from the end of

§ 413.230(b). We proposed that the ''and'' would be added to the end of § 413.230(d).

In addition, we proposed to revise the definition of ESRD outlier services at § 413.237(a)(1) by adding a new paragraph (a)(1)(v) to include renal dialysis equipment and supplies that receive the TPNIES as specified in § 413.236 after the payment period has ended. We proposed to redesignate existing paragraph (a)(1)(v) as paragraph (a)(1)(vi) and revise the paragraph to state ''As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.'' We proposed this technical edit to reflect an order in the definition of ESRD outlier services as first, items and services included and second, items and services that are excluded.

We also proposed technical changes to § 413.237(a)(1)(i) through (iv) to replace the phrases ''ESRD-related'' and ''used in the treatment of ESRD'' with ''renal dialysis'' to reflect the current terminology used under the ESRD PPS and to replace the word ''biologicals'' with ''biological products'' to reflect FDA's preferred terminology.

The comments and our responses to the comments on our proposals regarding pricing of new and innovative renal dialysis equipment and supplies and the proposed changes to ESRD PPS regulations are set forth below. We did not receive comments on our proposal to add paragraph (e) to § 413.230 to reflect the TPNIES, for a technical change to remove ''and'' from the end of § 413.230(b), for a technical change to include ''and'' to the end of § 413.230(d), or the technical changes to § 413.237(a)(1)(i) through (iv) to replace the phrases ''ESRD-related'' and ''used in the treatment of ESRD'' with ''renal dialysis'' to reflect the current terminology used under the ESRD PPS and to replace the word ''biologicals'' with ''biological products'' to reflect FDA's preferred terminology. We are therefore finalizing these revisions to the regulation text as proposed.

Comment: Most commenters, including a national dialysis stakeholder organization, an LDO, a nursing association, a device manufacturers association and a patient advocacy organization expressed concern that after the 2-year TPNIES period, we did not propose to make changes to the base rate. Rather, we proposed to make these items eligible for outlier payments. Several commenters asked that CMS adjust the base rate to include dollars for the incremental difference of the cost of the new device and what may be reflected in the ESRD PPS base rate already. They asserted that this comprehensive approach is the best way to align the TPNIES policy with the President's goal to incentive the adoption of new innovations in the ESRD program. In addition, MedPAC stated that CMS should not make duplicative payments for new ESRD-related equipment and supplies by paying under the TPNIES for 2 years and paying for an item with a similar purpose or use that is already paid under the ESRD PPS base rate. For example, CMS could reduce the TPNIES payment amount to reflect the amount already included in the base rate. An LDO also made this suggestion.

The LDO suggested that CMS should apply funds not expended under the narrower TDAPA eligibility policy to make ESRD PPS adjustments when it adds new products to the ESRD PPS base rate. An adjustment could be established that equals the incremental difference between any amounts associated with the functional category currently in the base rate attributable to the new product's cost. The LDO noted that this might result in CMS adding the product's full cost if the base rate does not include any such reimbursement or a lesser amount that reflects current dollars in the base rate. The LDO also recommended that CMS make similar adjustments to ensure that the base rate reflects costs associated with a new device after a TPNIES ends.

A device manufacturer suggested that, at the end of the TPNIES period, CMS positively adjusts the ESRD PPS base rate to reflect the added value of the TPNIES product. For example, CMS could adjust the ESRD PPS via a value-based modifier adjustment by exercising its authority under section 1881(b)(14)(D)(iv) of the Act to adjust payments under the ESRD PPS for value-enhancing medical products following the expiration of the transitional pass-through period. The value-based modifier could be derived from the demonstrated value of a given TPNIES product—for example, a device's demonstrated impact on averting hospitalizations and other additional resources. The manufacturer suggested that value could be shared between facilities using the new device and the Medicare program.

The patient advocacy organization expressed concern that by leaving a funding ''cliff'' at the end of the 2-year TPNIES period, clinics may not test new products. The organization also expressed concern that if the device reduces complications and thereby reduces the total cost of care for ESRD patients, but that these savings are not reflected in the fee-for-service (FFS) payment system, the device will be offered to Medicare Advantage enrollees but not to FFS beneficiaries.

Another commenter recommended collection of use data similar to that collected under the TDAPA policy for new renal dialysis drugs and biological products that are in new ESRD PPS functional categories, and if a product is used by a sufficient proportion of Medicare beneficiaries, CMS should increase the ESRD PPS base rate.

A national dialysis association, a device manufacturers association and a device manufacturer also recommended that at the end of the TPNIES period, CMS positively adjust the ESRD PPS base rate to reflect the added value of the TPNIES product. The commenters stated that failure to positively adjust the ESRD PPS base rate after the TPNIES period will result in a situation where providers must absorb the costs of the new product after the expiration of the add-on payment adjustment. This could discourage providers from adopting the new device in the first instance or from using the device for the long-term. The commenters noted that both outcomes would hinder innovation and stall improvements in patient care, which undercuts the fundamental purpose of the TPNIES. The organization stated that the outlier pool was never designed to provide comprehensive reimbursement for new, high-cost products to a significant number of beneficiaries. The outlier pool cannot function as a substitute for thoughtfully building dollars into the base rate to cover expected care.

An LDO disagreed that it would be inappropriate to add new dollars to the ESRD PPS base rate at the end of the TPNIES timeframe. The LDO is concerned that the TPNIES will encourage uptake of high-cost new technologies and then leave providers without a way to cover the costs above the amount accounted for in the base rate after the 2-year window closes. The LDO stated that the outlier policy does not address this funding shortfall and would exclude lower cost innovative supplies that do not exceed the FDL threshold. In addition, although the LDO has longstanding concerns with the outlier mechanism, the LDO agreed that device technologies (like drugs) should be part of the outlier payment mechanism, as they are for other Medicare providers, to address individual high cost cases.

While the LDO agrees that it is not the intent of the PPS to add new money whenever something new is made available, the LDO expressed concern that the current policy does not leave

CMS any flexibility to do so when appropriate and is a significant disincentive for technology developers to enter the ESRD space. The LDO recommended that CMS establish a process for adding dollars into the base rate, where appropriate, to ensure PPS payments are sufficient to reflect improved technologies once the TPNIES timeframe ends. In addition, CMS should finalize its proposal to add TPNIES-eligible products to its definition of ESRD outlier services to account for individual high cost cases.

Response: We appreciate the concerns raised by the stakeholders with regard to our proposal to not adjust the ESRD PPS base rate after the end of the TPNIES period. As we explained in the CY 2020 ESRD PPS proposed rule, sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. When implementing the ESRD PPS for CY 2011, we used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate (75 FR 49075). Therefore, we believe the ESRD PPS base rate currently reflects the renal dialysis equipment and supplies that will be eligible for TPNIES.

Moreover, as we have explained with respect to the TDAPA for drugs already reflected in the ESRD PPS functional categories, we believe adding dollars to the ESRD PPS base rate for items that are already reflected in the ESRD PPS base would be inappropriate and would be in conflict with the fundamental principles of a PPS. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's cost, which creates an incentive for cost control. It is not the intent of a PPS to add dollars to the base rate whenever something new is made available. Additionally, the statute does not require that we add dollars to the ESRD PPS base rate when a new item is available.

With regard to the comment about CMS using a value-based modifier adjustment, as we explained in the CY 2020 ESRD PPS proposed rule, the intent of the TPNIES for new and innovative equipment and supplies is to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative equipment and supplies. For example, when new and innovative equipment and supplies are introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a product and its effect on patient outcomes. We believe this uptake period would be supported by the TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS.

We appreciate the suggestion of reducing the TPNIES payment by the amount already included in the ESRD PPS base rate, however, ESRD facilities have historically not reported on claims the utilization of composite rate items and services, which is what these products are considered to be. Therefore we do not have the data sufficient to make these calculations at this time. We note that we included a request for this information in section VIII.A of the CY 2020 ESRD PPS proposed rule on how to collect this data. In response some commenters stated that the composite rate components to price the cost of dialysis treatment was outmoded and unnecessary concept and counter to the objective of the bundled system instituted with the ESRD PPS in CY 2011.

We are concerned about the comment stating that ESRD facilities will choose to not adopt new and innovative equipment and supplies. We do not agree with these commenters because we believe that innovative products that are competitively priced and that add value will be able to be successfully marketed and that ESRD facilities will want to use them. In addition, since we collect monitoring data, we will be aware of utilization and behavior trends and will be able to use this data to inform future policies.

Comment: Most provider organizations including a national dialysis stakeholder organization, an LDO, a professional association, a nursing association and a national dialysis association requested that we provide the TPNIES for 2-full calendar years of cost and utilization data. They stated that patients and providers take time to integrate new technologies and innovation into ongoing care practice. To ensure that cost and utilization data are accurate, they recommended that CMS extend the TPNIES period for the time required to collect 2 full years of cost and utilization data.

However, a device manufacturer association and a medical technology company requested that we extend the TPNIES period to 4 years. They opined that a 2-year period would discourage small start-up companies from developing innovative equipment and supplies, as building the support and distribution infrastructure nationwide to support new technology implementation takes far longer. They stated that extending the coverage period to 4 years would help level the playing field between small innovators and large, global manufacturers with an existing support and distribution footprint. Several other commenters recommended a 3-year TPNIES period because facilities need several years to set up system modifications and adjust business practices. They stated they believe that at least 3 years is an appropriate timeframe based on CMS' experience with other new technology add-on payment mechanisms.

Response: In providing an add-on payment, that is, the TPNIES, for new and innovative renal dialysis equipment and supplies that are accounted for in the ESRD PPS base rate, we did not propose to incorporate these products into the ESRD PPS base rate when the TPNIES period ends. The purpose for the TPNIES is to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative equipment and supplies. For example, when new and innovative renal dialysis equipment and supplies are introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies can be unpredictable with regard to their uptake and pricing, which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a product and its effect on patient outcomes. We believe this uptake period would be supported by the TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS. The TPNIES would target payment for the use of new and innovative renal dialysis equipment and supplies during the

period when a product is new to the market.

Further, we believe that the 2-year period gives the ESRD facility the opportunity to incorporate the product into their business model if they choose. The facility would be comparing a product currently in use with a new and innovative product and making a choice if the increased cost would be commensurate with increased clinical value to the beneficiary. We continue to believe providing the TPNIES for 2 years is appropriate for new and innovative products and that a longer timeframe to establish the product's uptake is not necessary, particularly since the ESRD PPS base rate includes money for these products. We are not expanding the duration of the TPNIES period because we believe that 2 years strikes the appropriate balance of supporting innovation while protecting the Medicare expenditures. We note that the TPNIES period begins on January 1, the effective date of the annual ESRD PPS final rule in which we announce our determinations with regard to TPNIES applications, and ends on December 31, that is, 2 years later.

Comment: Many comments expressed support for the proposal to base payment for the TPNIES on the price established by the MACs using information from invoices and other relevant sources of information. However, MedPAC expressed support for the proposal but only for the first 2-calendar quarters after CMS begins applying the TPNIES. Thereafter, MedPAC recommended that CMS should set the price of new equipment and supplies using a method based on pricing data collected directly from each manufacturer, similar to how CMS establishes the average sales price (ASP) for Part B drugs.

The Commission pointed out that the ASP for a Part B drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. There is a 2-quarter lag in the data used to set ASP-based payment rates. MedPAC stated that an approach similar to how CMS collects ASP data would increase the consistency of pricing data and should lead to more accurate payment rates for items paid under the TPNIES. In establishing a process for collection of average sales price data for equipment and supplies, the Commission recommended that, similar to the TDAPA for new renal dialysis drugs and biological products, CMS should link payment of the TPNIES to a requirement that equipment and supply manufacturers submit ASP-like data to CMS.

Other commenters, including a device manufacturer, a device manufacturers association, and a patient advocacy organization recommended that, instead of the invoice-based pricing process at the MAC level, with possible national-level rates set once there is enough data across multiple MACs, CMS adopt a rate determination process like the NTAP. Under this process, TPNIES applicants, when providing SCI data and other information in their application, can also provide information on the cost of the product. Then, when CMS discusses the application in the ESRD PPS proposed rule, CMS could discuss the cost information provided by the applicant and ask stakeholders (including providers, innovation leaders and patient-centered advocacy organizations) for comments. The national payment rate could then be finalized in the ESRD PPS final rule when CMS accepts or denies the TPNIES application. The commenters indicated that this change in process would elevate the principle and practice transparency and provide far greater certainty for ESRD providers and, more importantly, limit the impact of the TPNIES administrative process on patient access.

A national dialysis stakeholder organization and an LDO asked that CMS ensure that the pricing for the TPNIES is transparent and provides predictability and consistency in pricing. A professional association stated that by their very nature, MACs make local coverage and reimbursement decisions that can vary by region. To ensure consistency and adequacy in pricing and reimbursement, they urged CMS to ensure that the proposed MAC pricing process is transparent and understandable for all stakeholders. Another LDO agreed and requested that CMS specify in the CY 2020 ESRD PPS final rule that MACs must disclose the sources of information relied on (without disclosing proprietary information) so stakeholders can understand the basis for pricing determinations as well as any variations in prices jurisdictions.

A national dialysis association recommended that the MACs should use a transparent, notice-and-comment process in order to establish the reimbursement associated with the TPNIES. The association stated that if the MACs cannot accommodate a notice-and-comment process, then CMS should consider an alternative process for the establishment of reimbursement policy that would ensure the opportunity for notice-and-comment to the public.

Response: As we stated in the CY 2020 ESRD PPS proposed rule, at this time, we do not have the data to set a price for new and innovative renal dialysis equipment and supplies. We note that there are other times when items and services do not have fee schedule payment rates assigned to them that are paid under Medicare via a MAC-determined value, for example, when new drugs do not have an ASP. We agree with the commenters that transparency and predictability is important, however, we would need time to develop a national price for a particular product. We note that in comparison to IPPS's NTAP policy, we do not apply the ESRD PPS outlier policy during the TPNIES period, which makes process we have laid out for determining the price more predictable than the IPPS. With regard to MedPAC's suggestion for an ASP-like data reporting system, we do not have sufficient data at this time to develop such a system, but will take the comment into consideration for future rulemaking.

With regard to the comments that we rely solely on the manufacturer's estimated cost to the facility and public comments to establish a national payment amount for a TPNIES equipment or supply, we are requesting that manufacturers estimate the cost of the equipment or supply to the facility on a per treatment basis in the application. However, while we believe this information from the manufacturer is one factor in the MAC price determination process, we do not believe it would be appropriate to set a national price based solely on that information. As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38355), the MAC-determined price would be established using verifiable information from the following sources of information, if available: The invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We did not propose to establish a national price because we do not have historical cost data and we are only in the initial phases of developing a

process to evaluate cost criteria. However, we will consider this idea for future rulemaking.

Comment: While most commenters expressed support for the TPNIES proposal to pay 65 percent of the MAC-determined price, an organization of LDOs and an LDO suggested that CMS consider whether or not the innovation replaces a product currently reflected in the ESRD PPS base rate and take a more customized approach in establishing a product's TPNIES amount. They also stated that the proposed TPNIES payment of 65 percent of prices obtained from invoices or other relevant data sources might be sufficient for a product that replaces one included in the ESRD PPS bundled payment. However, they noted it will likely fall short in covering the costs of a completely new and innovative product. The commenters stated that with ESRD facilities' negative margins, facilities will have little room to absorb these costs, which will compromise the adoption of, and beneficiaries' access to, truly innovative products. They further stated that it is possible that for new devices, 65 percent of the MAC-determined price will sufficiently cover facility costs. They asked that CMS monitor this policy and leave open the possibility of amendments, as needed, to ensure that clinically valuable, new technology can actually reach beneficiaries.

A device manufacturer and a device manufacturers association and others urged CMS to pay 100 percent of the cost of the new product to ensure maximum adoption of the new TPNIES product, and to compensate for any unforeseen costs associated with that product. The commenters stated that the ESRD PPS bundled payment for thrice-weekly dialysis care is a model that encourages efficiency among existing services and inputs but discourages investment in new technologies that offer a new value proposition. They asserted that providing 65 percent of the known costs of the new device through TPNIES does not provide payment for any unanticipated costs of the new technology such as additional staff training, product administration, or facility handling.

In addition, the commenters pointed out that there is a significant lag in payment that requires facilities to assume liability for any excess costs associated with a new device above the ESRD PPS bundled payment amount. Thus, the commenters opined that new devices create a dilemma for providers under the ESRD PPS: Either absorb the costs associated with a new technology to advance the standard of care or forego the new technology despite its clinical benefits. For these reasons, they urged CMS to set the payment adjustment at 100 percent of the cost of the new TPNIES approved product.

However, MedPAC expressed support for the proposal to pay a reduced percentage of the new item's cost as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices. MedPAC also recommended that CMS not explicitly link the ESRD PPS TPNIES payment percentage to the IPPS NTAP mechanism's maximum add-on payment percentage. The Commission pointed out that CMS would have greater flexibility about any future changes to the ESRD PPS payment percentage if it was not explicitly linked to the IPPS payment percentage.

Response: We appreciate the support for the proposal to pay 65 percent of the MAC-determined price and agree with MedPAC that this would disincentivize high launch prices. At this time, we are not finalizing a policy to explicitly tie the ESRD PPS to future changes to the IPPS NTAP policy with regard to the IPPS NTAP mechanism's maximum add-on payment amount percentage. However, we believe that we have the same goal as the IPPS with regard to supporting ESRD facility use of new and innovative renal dialysis equipment and supplies. In addition, we agree with MedPAC that the TPNIES amount needs to be a value that is enough to incentivize uptake of the new and innovative equipment or supply by ESRD facilities but believe that we need to balance this with sharing risk for the new product. We agree with commenters with regard to monitoring utilization of these products that are eligible for the TPNIES and we note that any future changes to this policy would be addressed through notice and comment rulemaking.

Comment: MedPAC stated that CMS should publish in the final rule an estimate of the increase in beneficiaries' and taxpayers' spending due to the proposed policy change and the method used to develop the estimate.

Response: As we explain in section X of this final rule, the fiscal impact of Medicare and beneficiary spending cannot be determined due to the uniqueness of the new renal dialysis equipment and supplies eligible for the TPNIES and their costs.

Final Rule Action: After consideration of public comments, for CY 2020 we are finalizing the addition of § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply based on 65 percent of the MAC-determined price, as described in newly added § 413.236(e). The TPNIES will be paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237.

We are also finalizing the addition of § 413.236(e) to require that the MAC on behalf of CMS will establish prices for the new and innovative renal dialysis equipment and supplies described in newly added § 413.236(b), and that we will use these prices for the purposes of determining the TPNIES. The MAC will use verifiable information from the following sources of information, if available: (1) The invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

In addition, we are finalizing the proposed revision to the definition of ESRD outlier services at § 413.237(a)(1) by adding a new paragraph (a)(1)(v) to include renal dialysis equipment and supplies that receive the TPNIES as specified in § 413.236 after the payment period has ended. We are finalizing the redesignation of existing paragraph (a)(1)(v) as paragraph (a)(1)(vi) and the revision of the paragraph to state ''As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.''

iv. Implementation Process for CY 2020

We intend to develop an electronic application for the TPNIES over the next year. In the meantime, in order to implement the TPNIES for CY 2020 and provide an opportunity for equipment and supply manufacturers to apply for TPNIES payment for CY 2021, we are providing in this final rule certain technical instructions for applications submitted in CY 2020. In addition, we will provide these instructions on a new CMS web page under development for the TPNIES.

Deadline

Submit a complete application with a response to each question below no later than February 1, 2020. An application is considered complete when all of the information requested has been submitted by the date specified and when questions related to the

submission have been answered by the applicant.

Address To Send Applications

Mail four copies of the completed applications to the following address: ESRD PPS TPNIES Application, Division of Chronic Care Management, Centers for Medicare and Medicaid Services, M/S C5–05–07, 7500 Security Blvd., Baltimore, MD 21244–1850.

Additionally, submit an electronic version of the application via email to *ESRDPayment@cms.hhs.gov.* Emailed versions of the materials must be compatible with standard CMS software such as Adobe Acrobat DC for 2015 or Microsoft Word 2010. The subject line of the email must say ESRD PPS TPNIES application. Total attachments in one email must not exceed 20 megabytes. If necessary, send multiple emails with attachments less than 20 megabytes. Questions pertaining to the TPNIES process may also be sent to the electronic mailbox noted above.

Required Information

Applications must include a response to each question below. CMS may request other information to evaluate specific TPNIES requests. A separate application is required for each distinct equipment or supply included in the TPNIES request.

1. Name, address, telephone number, and email address for the primary and backup contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant's contact information.

2. Trade/brand name of the equipment or supply.

3. Describe the technology in general terminology—What is it? What does it do? How is it used? Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new equipment or supply.

4. Have you submitted an application for pass-through payments under the Medicare outpatient prospective payment system or new technology payments under the IPPS? If so, please provide the tracking number or, if it was approved, please provide the date of approval.

5. Under what pathway are you seeking marketing authorization from FDA? What is the date of anticipated FDA marketing authorization for the equipment or supply? Provide a copy of the FDA marketing authorization. If marketing authorization has not yet been granted, provide a copy of the authorization to CMS immediately after it becomes available.

Per 42 CFR 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by September 1 prior to the beginning of the calendar year (CY) for which the TPNIES would be effective (for CY 2021 payment, not later than September 1, 2020).

6. List the name and telephone number or email address of a contact at FDA who is knowledgeable about the submission for marketing authorization for the new equipment or supply listed above.

7. Will the equipment or supply be available on the market immediately after FDA marketing authorization? If not, provide the date that the equipment or supply came on the market (that is, first sales or availability) and an explanation and documentation of any anticipated delay (for example, manufacturing issues or other reasons). If commercial availability has not yet occurred, provide proof of commercial availability to CMS immediately after it becomes available, for example, a manufacturer's bill of sale. Note that the manufacturer must inform CMS by September 1 if the equipment or supply will not be available by January 1.

8. Is there an investigational device exemption number from the FDA assigned to the equipment or supply? If yes, please provide this code. Refer to *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm* for more details.

9. What class (I, II, or III) was/is assigned to the equipment or supply? Refer to *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm* for more details.

10. Has an application for an HCPCS code been submitted? If not, please note that submission of the HCPCS application is required by September 1, 2020, so that we are able to use information from the HCPCS application in our determination process. Refer to *http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html* for more information.

11. What is the anticipated cost of the equipment or supply to the ESRD facility, per treatment? Provide a breakdown of how the cost of the new equipment or supply is calculated.

12. What is the anticipated Medicare and Non-Medicare volume of this equipment or supply for the 2 years in the TPNIES period? Describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your equipment or supply, not the total population eligible for the equipment or supply.

Note: Applicants are not required to submit proprietary or confidential information as part of the application. However, an applicant may choose to include such information to support its request. Applicants should note that information they include in an application is not explicitly protected from disclosure in response to a Freedom of Information Act (FOIA) request. However, FOIA does include an exemption for trade secrets and commercial and financial information obtained from a person that is privileged or confidential.

Once the information requested by CMS is received and reviewed, for equipment and supplies eligible for the TPNIES, we will issue a change request with billing guidance that will provide notice that the equipment or supply is eligible for the TPNIES as of January 1 and technical instructions on how to report the equipment or supply on the ESRD claim. This change request will initiate the TPNIES period and it will end 2 years from the change request's effective date.

c. Comment Solicitation on Payment for Renal Dialysis Humanitarian Use Devices (HUD)

Medical devices and related innovations are integral in meeting the needs of patients, especially the most vulnerable patients, such as ESRD patients and those with rare medical conditions. While FDA determines which devices are authorized for marketing, public healthcare programs such as Medicare determine how these products will be covered and paid, which can affect patient access to new and innovative products.

In the CY 2020 ESRD PPS proposed rule (84 FR 38357), we solicited comments on Medicare payment for renal dialysis services that have a Humanitarian Use Device (HUD) designation. Under FDA regulations (21 CFR 814.3(n)), a HUD is a ''medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.'' We explained in the CY 2020 ESRD PPS proposed rule that Medicare has no specific rules, regulations or instructions with regard to HUDs. We noted that we were particularly interested in receiving comments on HUDs that would be considered renal dialysis services under the ESRD PPS, any barriers to payment encountered, and past experience in obtaining

Medicare payment for these items through the MACs.

We received 7 comments on this solicitation. The comments and our response are set forth below.

Comment: We received comments from a device manufacturer, a medical device manufacturing association, a drug manufacturer, a non-profit provider, a professional society, a national dialysis stakeholder organization and a patient advocacy organization.

The commenters noted that in 1990, Congress created the HUD program to encourage the research, development and marketing of innovative devices for the treatment of rare diseases or conditions where no comparable devices are available to those patients. They stated that lack of Medicare reimbursement for HUDs impedes access to these treatments for Medicare beneficiaries. They also stated that CMS should ensure that HUDs are eligible for Medicare reimbursement, and suggested that a Congressional directive that HUDs be sold by manufacturers at cost indicates that CMS should establish Medicare payment for HUDs at invoice.

A medical device manufacturing association and a patient advocacy organization noted that there should be Medicare coverage of HUDs and payment for these devices under the ESRD benefit if such devices are required to be used in the ESRD facility, whether they are for the treatment of ESRD or for the treatment of other conditions related to renal dialysis.

A drug manufacturer noted its understanding that the HUD program is a specific FDA program, but encouraged CMS to work with the company and other innovators to protect access to innovative products that treat a disease or condition affecting a very small number of individuals in the U.S. annually. The company noted that drugs that are administered to a small percentage of patients cannot be accounted for properly in a bundled payment system. If dollars are allocated across all patients, then those who require the drug may not receive the care they need because the providers administering it will not have sufficient funds, while those providers who do not provide the product will see a small increase in their base rate. The company stated that money should follow the patient in these circumstances to protect access to drugs that benefit a small number of patients.

A device manufacturer urged CMS to promulgate a regulation clarifying that HUDs are within the definition of renal dialysis services or dialysis services depending on the device's function, and explicitly define that HUDs should be reimbursed based on invoice given that Congress has already addressed the invoice price to be charged. A patient advocacy group urged CMS to ensure a reimbursement pathway for devices with a HUD designation.

Response: We appreciate the range of comments we received on this issue. We will consider these comments carefully as we contemplate future policies related to HUDs.

4. Discontinuation of the ESA Monitoring Policy (EMP) Under the ESRD PPS

a. Background

In the CY 2011 ESRD PPS final rule (75 FR 49067, 49145 through 49147), CMS adopted the ESA monitoring policy (EMP) under the ESRD PPS for purposes of calculating the base rate and for establishing the outlier policy's percentage and thresholds.

For purposes of calculating the CY 2011 ESRD PPS base rate, payments for ESAs were capped based on determined dose limits as discussed in the Medicare Claims Processing Manual (chapter 8, section 60.4.1). Payments for epoetin alfa in excess of 500,000 units per month in 2007 were capped at 500,000 units and a similar cap was applied to claims for darbepoetin alfa, in which the caps were based on 1,500 mcg per month in 2007 (75 FR 49067).

As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38357 through 38358) with regard to the application of the outlier policy, since ESAs are considered to be an ESRD outlier service under § 413.237(a)(1)(i), covered units are priced and considered toward the eligibility for outlier payment consistent with § 413.237(b). That is, we apply dosing reductions and ESA dose limits consistent with the EMP prior to any calculation of outlier eligibility. Medicare contractors apply a 25 percent reduction in the reported ESA dose on the claim when the hemoglobin (or hematocrit) level exceeded a certain value, unless the ESRD facility reported a modifier to indicate the dose was being decreased. Also under the EMP, ESRD facilities are required to report other modifiers to indicate a patient's 3-month rolling average hemoglobin (or hematocrit) level so that the Medicare contractor knows when to apply a 50 percent reduction in the reported ESA dose on the claim. In addition to these dosing reductions, we apply ESA dose limits as discussed in the Medicare Claims Processing Manual (chapter 8, section 60.4.1) prior to any calculation of outlier eligibility.

When we adopted the EMP for the ESRD PPS in the CY 2011 ESRD PPS final rule, we explained that the continued application of the EMP would help ensure the proper dosing of ESAs and provide a safeguard against the overutilization of ESAs, particularly where the consumption of other separately billable services may be high, in order to obtain outlier payments (75 FR 49146). In the CY 2020 ESRD PPS proposed rule, we explained that due to implementation of the ESRD PPS and FDA relabeling of epoetin alfa, which stated that the individualized dosing should be that which would achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL, we no longer believed application of the EMP is necessary to control utilization of ESAs in the ESRD population. That is, the impact of no longer paying separately for ESAs, which discourages overutilization, along with practitioners prescribing the biological product to maintain a lower hemoglobin level, has resulted in a decline in its utilization and a stringent monitoring of the biological product's levels in patients.

b. Discontinuing Application of the EMP to Outlier Payments Under the ESRD PPS

CMS proposed that, effective January 1, 2020, we would no longer apply the EMP under the ESRD PPS. As we explained in the CY 2020 ESRD PPS proposed rule, since the implementation of the ESRD PPS, ESA utilization has decreased significantly because the structure of the PPS removed the incentives to overuse these biological products. Under our proposal, ESRD facilities would no longer be required to report the EMP-related modifiers and Medicare contractors would no longer apply dosing reduction or dose limit edits to ESA dosing. Therefore, these edits would no longer be applied prior to calculation of outlier eligibility and would no longer be reflected in outlier payments.

We stated that we would continue to require ESRD facilities to report all necessary information for the ESRD Quality Incentive Program, and noted that, as part of managing the ESRD PPS, CMS has a monitoring program in place that studies the trends and behaviors of ESRD facilities under the ESRD PPS and the health outcomes of the beneficiaries who receive their care.[33] We stated that if we finalize this proposal, we would continue to monitor the utilization of

[33] ESRD PPS Claims-Based Monitoring Program. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Claims-Based-Monitoring.html.*

ESAs to determine if additional medically unlikely edits are necessary. In addition, we noted that with the increased use of certain phosphate binders that have the secondary effect of anemia management, CMS would closely monitor ESA usage in conjunction with phosphate binder prescribing and usage.

We stated in the CY 2020 ESRD PPS proposed rule that we believed discontinuing this policy would reduce burden for ESRD facilities because the EMP provides an opportunity for appeal to address those situations where there might be medical justification for higher hematocrit or hemoglobin levels. Beneficiaries, physicians, and ESRD facilities are required to submit additional documentation to justify medical necessity, and any outlier payment reduction amounts are subsequently reinstated when documentation supports the higher hematocrit or hemoglobin levels. Thus, we explained that this proposal would reduce the documentation burden on ESRD facilities because they would no longer have to go through the EMP appeal process and submit additional documentation regarding medical necessity.

The comments and our responses to the comments on our proposal to discontinue the application of the EMP under the ESRD PPS are set forth below.

Comment: Several commenters were supportive of the proposal to no longer apply the EMP under the ESRD PPS. The commenters agreed with the underlying rationale that the EMP is no longer needed because ESAs have been incorporated into the ESRD PPS. Some of the commenters asked that we confirm that hemoglobin or hematocrit value codes are still required on Medicare claims.

Response: We appreciate the commenters' support. With regard to the reporting of hemoglobin or hematocrit value codes, ESRD facilities are required to continue to report all necessary information for the ESRD Quality Incentive Program under the ESRD PPS, which includes hemoglobin or hematocrit values.

Comment: MedPAC and a software company opposed the proposal. The software company stated that in its efforts to better manage hemoglobin cycling in the ESRD population, the company has found there is an opportunity to further reduce overutilization, cut drug waste, and decrease hospitalizations. The company strongly encouraged CMS to preserve the EMP for this reason.

MedPAC stated that the implementation of the ESRD PPS created incentives for ESRD facilities to furnish services more efficiently. MedPAC stated that under the ESRD PPS, in which all renal dialysis drugs and biological products are included in the payment bundle, ESRD facilities have been more judicious in providing all drugs, including ESAs. For example, MedPAC stated that between 2010 and 2017, use of all renal dialysis drugs and biological products paid under the ESRD PPS has declined by 12 percent per year. MedPAC noted that the decline in the use of ESRD drugs under the PPS has occurred without any negative effect on clinical outcomes.

MedPAC stated that by contrast, the TDAPA, which is an add-on payment adjustment for nearly all renal dialysis drugs and biological products that FDA approves on or after January 1, 2020, may promote excess provision of renal dialysis drug products (to the extent clinically possible). MedPAC explained that paying according to the number of units administered gives ESRD facilities greater profits from larger doses than smaller doses (as long as Medicare's payment rate exceeds providers' costs). MedPAC expressed concern that in addition to increased and unnecessary spending for beneficiaries and taxpayers, overuse of drugs can have negative clinical consequences. MedPAC stated that because of the incentive for potential overuse of drugs paid under the TDAPA policy, CMS should not discontinue the EMP. MedPAC urged CMS to establish a formal monitoring policy for all renal dialysis drugs and biological products that are paid under the TDAPA to address their potential for overuse.

Response: We appreciate the software company's comment that there may still be an opportunity to further reduce overutilization, cut drug waste, and decrease hospitalizations. According to the ESRD PPS monitoring data [34] that is available to the public on the CMS website, we have found that ESA utilization has declined since the implementation of the ESRD PPS with no sustained negative changes in beneficiary health status. We believe that this finding indicates, overall, that patients are not suffering negative health consequences and that the EMP adds a layer of unnecessary burden for ESRD facilities at this time.

With regard to MedPAC's concern that renal dialysis drugs and biological products eligible for the TDAPA may increase unnecessary spending for beneficiaries and taxpayers, in addition to potential negative clinical consequences, we will take these concerns into consideration for future monitoring policies. We believe that with near-real-time claims monitoring we have the ability to closely track ESRD facility behaviors and can take action if we see something concerning.

Final Rule Action: After consideration of public comments, we are finalizing the proposal to no longer apply the EMP under the ESRD PPS effective January 1, 2020. We will issue administrative guidance to provide instructions on the technical changes to the claims processing requirements.

5. CY 2020 ESRD PPS Update

a. CY 2020 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share for ESRD PPS

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162). In the CY 2015 ESRD PPS final rule we rebased and revised the ESRDB input price index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

[34] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Claims-Based-Monitoring.html.*

We proposed to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2020 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI) most recently available forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. Using this methodology and the IGI first quarter 2019 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2018), the proposed CY 2020 ESRDB market basket increase factor was 2.1 percent.

Under section 1881(b)(14)(F)(i) of the Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. We finalized the detailed methodology for deriving the MFP projection in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf*. Using this methodology and the IGI first quarter 2019 forecast, the proposed MFP adjustment for CY 2020 (the 10-year moving average of MFP for the period ending CY 2020) was projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2020 ESRD market basket adjusted for MFP was 1.7 percent. This market basket increase is calculated by starting with the proposed CY 2020 ESRDB market basket percentage increase factor of 2.1 percent and reducing it by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending CY 2020) of 0.4 percent.

The comments and our responses to the comments on the proposed productivity-adjusted market basket annual update and MFP adjustment for CY 2020 are set forth below.

Comment: One commenter expressed appreciation for the proposed increase to the ESRD PPS base rate for CY 2020, but expressed concern that the proposed amount will not fully cover costs associated with providing high-quality care to patients, particularly by small and independent providers with limited resources offering care in many cases to patients in rural and underserved areas where access challenges may be present.

Response: We appreciate the commenter's concern that the proposed annual update factor may not be sufficient to cover the cost of care for small independent providers or those in rural areas. The annual update factor is intended to account for the overall increase in cost of care at the national level. The patient case-mix payment adjustments and the facility level adjustments, such as the rural adjustment and low-volume payment adjustment account for differences in both patient and facility characteristics. These payment adjustments are provided to address the variation of costs of a particular facility relative to the national standard.

Comment: One LDO reiterated its concerns submitted in response to the CY 2019 ESRD PPS proposed rule (83 FR 56961) related to the ability of ESRD facilities to achieve and maintain high levels of productivity gains. The LDO noted that several factors impact the potential for productivity gains including required staffing level minimums and the unique nature of contracted versus employed labor in the ESRD setting. The commenter stated that the current MFP adjustment is a crude measure that does not reflect circumstances unique to ESRD facilities. The LDO further stated that it seeks to engage with CMS to support developing an ESRD-specific MFP in collaboration with Congress and the Bureau of Labor Statistics (BLS).

Response: Section 1881(b)(14)(F)(i) of the Act requires the application of the MFP adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act, to the ESRD PPS market basket update for 2012 and subsequent years. The statute does not provide the Secretary with the authority to apply a different adjustment. We will continue to monitor the impact of the payment updates, including the effects of the MFP adjustment, on ESRD provider margins as well as beneficiary access to care as reported by MedPAC. However, as noted previously, any changes to the MFP adjustment would require a change to current law.

The March 2019 MedPAC Report to Congress finds, ''Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital. Providers have become more efficient in the use of dialysis drugs under the PPS.'' (*http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch6_sec.pdf?sfvrsn=0*).

While we understand that the kidney care community is interested in an adjustment more specific to ESRD facilities, we encourage commenters to discuss the feasibility of such measures with the BLS, the agency that produces and publishes industry-level MFP. CMS is unable to estimate MFP for ESRD facilities since the publicly available data for the NAICS 621492 Kidney Dialysis Centers is insufficient to develop an estimate using a similar methodology used to estimate Hospital sector MFP in the November 2006 Health Care Financing Review article, '' 'Hospital Multifactor Productivity: A Presentation and Analysis of Two Methodologies' ''. We would also encourage the kidney care community to make available to CMS any research into alternative methods and data sources that could be used to estimate ESRD-specific MFP. Specifically, we would be interested in any information on how cost report data submitted to CMS could be utilized to better understand the operating conditions facing ESRD facilities.

Based on public comments and in accordance with section 1881(b)(14)(F)(i) of the Act, we are finalizing the CY 2020 update to the ESRD facilities as proposed. Also, as noted in the proposed rule and consistent with CMS general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket update or MFP adjustment), we proposed to use such data to determine the final CY 2020 market basket update and/or MFP adjustment. Therefore, using the IGI third quarter 2019 forecast of the CY 2016-based ESRDB market basket (with historical data through the second quarter of 2019), the final CY 2020 ESRDB market basket increase factor is projected to be 2.0 percent. The final MFP adjustment for CY 2020 (the 10-year moving average of MFP for the period ending CY 2020) is projected to be 0.3 percent. The final CY 2020 ESRD market basket adjusted for MFP is projected to be 1.7 percent. This market basket increase is calculated by starting with the CY 2020 ESRDB market basket percentage increase factor of 2.0 percent and reducing it by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2020) of 0.3 percent.

For the CY 2020 ESRD payment update, we proposed to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final

rule (83 FR 56963). We did not receive any public comments on this proposal and therefore are finalizing the continued use of a 52.3 percent labor-related share.

b. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) core-based statistical area (CBSA)-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/bulletins/*.

For CY 2020, we updated the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We used the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The final CY 2020 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final CY 2020 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html*.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38359), beginning in CY 2020, the statewide urban average based on the average of all urban areas within the state also will be applied to the Carson City, Nevada CBSA.

A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a policy to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We stated that we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 ESRD PPS proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which stakeholders could provide useful input for consideration in future decision-making. Specifically, we solicited comment on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, we finalized a wage index floor of 0.4000 in the CY 2017 ESRD PPS final rule (81 FR 77858).

In the CY 2018 ESRD PPS final rule (82 FR 50747), we finalized a policy to permanently maintain the wage index floor of 0.4000, because we believed it was appropriate and provided additional payment support to the lowest wage areas. It also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates.

In the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we finalized an increase to the wage index floor from 0.4000 to 0.5000 for CY 2019 and subsequent years. We explained that we revisited our evaluation of payments to ESRD facilities located in the lowest wage areas to be responsive to stakeholder comments and to ensure payments under the ESRD PPS are appropriate. We provided statistical analyses that supported a higher wage index floor and finalized an increase from 0.4000 to 0.5000 to safeguard access to care in those areas. We further explained that we believe a wage index floor of 0.5000 strikes an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. Thus, for CY 2020, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38360), we were made aware of a minor calculation

error in the file used to compute the ESRD PPS wage index values for the proposed rule. We posted the corrected wage index values on the ESRD PPS payment page and used the corrected values when computing the ESRD PPS wage index values and payment rates for this final rule.

CMS received several comments on the wage index. The comments and our responses are set forth below.

Comment: One LDO and one national dialysis association stated that CMS noted in the proposed rule that it was made aware of a ''minor calculation error'' in the file used to compute the ESRD PPS wage index values. The agency has since published a corrected file on the ESRD PPS payment web page.

They expressed concern that CMS has not published information to inform stakeholders about the impact of the updated ESRD wage index values on the ESRD PPS base rate. They stated that they believe a revised wage index budget neutrality factor, based on the revised wage indices, may result in a downward effect on the proposed base rate. As the labor-related share represents such a significant component of facility payment, they noted the importance of transparency and accuracy in proposed rates published by CMS so that providers and other stakeholders can understand the impact of proposed policy changes and provide input during the regulatory comment period. They recommended that CMS retain the prior year's wage indices to ensure consistency and transparency for stakeholders.

While the national dialysis association stated that it was able to run the complex calculations to determine the likely, corrected base rate and associated reimbursement factors, other stakeholders may not be able to utilize the technical files and available methodological information to re-run calculations and derive a corrected base rate. The association stated that independent analysis indicates that the wage index error published in the CY 2020 ESRD PPS proposed rule understated the wage adjustment amount by 0.84 percent across all calculations. The association stated that in the final rule, CMS should correct this error and simultaneously apply a corresponding, corrected budget neutrality factor that will reduce the proposed base rate by approximately $1 per treatment, resulting in approximately $41 million less for dialysis care in CY 2020 than was indicated in the CY 2020 ESRD PPS proposed rule.

The commenter suggested that if CMS discovers an error in the wage indices after publication of the proposed rule, the agency should provide the public with complete information, including the corrected wage indices, wage index budget neutrality factor, and revised ESRD PPS base rate.

Response: We thank the commenter for its comment that we understated the wage adjustment amount by 0.84 percent across all calculations. We note that the minor calculation error was that the wage and hour data for CBSA 31084 were inadvertently doubled. This caused an error in the national average hourly wage, which factors into the calculation of all wage index values. We have changed the programming logic to correct this error. In addition, we corrected the classification of one provider in North Carolina that was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency.

We also note that it is not uncommon for the ESRD PPS wage index values to change between the proposed and final rules. In this specific case, the proposed rule correction resulted in a wage index budget neutrality adjustment factor that lowered the base rate, but in the time between the proposed and final rule with updated wage index data, the wage index budget neutrality adjustment factor changed and the ESRD PPS base rate was increased. We make every effort to be fully transparent in our calculations and will continue to do so in the future.

Comment: Several health insurance organizations in Puerto Rico commented on the wage index for Puerto Rico, expressing that the historical downward trending of the ESRD PPS wage index is having a negative impact on the funding of Puerto Rico's dialysis program. The commenters stated that despite the 0.10 increase in 2019, there still remains a disparity gap. Currently, the USVI maintains a 0.70 ESRD wage index. The commenters noted that a movement towards parity funding between the two territories would be a significant step in narrowing the disparity-funding gap.

The commenters asserted that a wage index floor of 0.70 would result in rates that more accurately reflect actual cost per treatment based on costs after Hurricane Maria for the years 2018 and 2019. They believe that the average in-center hemodialysis costs for independent facilities in Puerto Rico is $232.25 per treatment using CMS data from 2017. They asserted that this number is significantly higher than the average FFS payment rate for Puerto Rico and significantly lower than the rates contracted by Medicare Advantage companies for the same service. They noted that in-center hemodialysis represents the majority of the treatments for Puerto Rico ESRD patients. In future reforms to the ESRD PPS wage index system, they suggested that CMS should use adjusted inpatient facility (Part A) wage index values to reverse the wage index ''downward spiral'' consistently across all Medicare payment systems. In addition, they stated that CMS should consider basing the ESRD PPS wage index on a new survey of ESRD outpatient facility wage costs. Finally, they recommended that CMS assure that the corresponding adjustment in Medicare Advantage benchmarks for ESRD is made to reflect any adjustments in FFS ESRD payments.

Response: We thank commenters for sharing their concerns regarding Puerto Rico's wage index and their opinion of an existing disparity gap, along with the recommendation of a wage index for Puerto Rico of 0.70 and their concern regarding the Medicare Advantage benchmarks for ESRD. We will take these thoughtful suggestions into consideration when considering future rulemaking.

Final Rule Action: We are finalizing the CY 2020 ESRD PPS wage indices based on the latest hospital wage data as proposed. For CY 2020, the labor-related share to which a facility's wage index is applied is 52.3 percent.

c. Final CY 2020 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would

have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described in the following paragraphs) plus the FDL amount. In accordance with § 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For CY 2020, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2018. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we proposed the outlier thresholds for CY 2020 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2018. We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38361) that we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS.

i. CY 2020 Update to the Outlier Services MAP Amounts and FDL Amounts

For this final rule, the outlier services MAP amounts and FDL amounts were updated using 2018 claims data. In the CY 2020 ESRD PPS proposed rule (84 FR 38361), we noted that, beginning in CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy (calculated to be $21.15 per treatment). For this final rule, we project that for each dialysis treatment furnished, the average amount attributed to the TDAPA is $21.03.

The impact of the final rule update is shown in Table 2, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2019 with the updated estimates for this final rule. The estimates for the final CY 2020 outlier policy, which are included in Column II of Table 2, were inflation adjusted to reflect projected 2020 prices for outlier services.

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TABLE 2: Outlier Policy: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2019 (based on 2017 data, price inflated to 2019)*		Column II Final outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$34.18	$40.18	$30.95	$37.33
Adjustments				
Standardization for outlier services	1.0503	0.9779	1.0655	0.9781
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$35.18	$38.51	$32.32	$35.78
FDL amount that is added to the predicted MAP to determine the outlier threshold	$57.14	$65.11	$41.04	$48.33
Patient-months qualifying for outlier payment	7.2%	8.2%	11.35%	10.38%

*Note that Column I was obtained from Column II of Table 11 from the CY 2019 ESRD PPS final rule (83 FR 56968).

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As demonstrated in Table 2, the estimated FDL amount per treatment that determines the CY 2020 outlier threshold amount for adults (Column II; $48.33) is lower than that used for the CY 2019 outlier policy (Column I; $65.11). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $38.51 to $35.78. For pediatric patients, there is a decrease in the FDL amount from $57.14 to $41.04. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $35.18 to $32.32.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2020 will be 10.38 percent for adult patients and 11.35 percent for pediatric patients, based on the 2018 claims data. The pediatric outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. For this final rule and based on the 2018 claims, outlier payments represented approximately 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2018 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2020.

We believe the update to the outlier MAP and FDL amounts for CY 2020 would increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy because we are using more current data for computing the MAP and FDL which is more in line with current outlier services utilization rates. We note that recalibration of the FDL amounts in this final rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments, as well as co-insurance obligations for beneficiaries with renal dialysis services eligible for outlier payments.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: MedPAC requested that CMS clarify the reference to calcimimetic payments being included in total expenditure amounts in the CY 2020 ESRD PPS proposed rule discussion of updating the outlier services MAP and FDL amounts. MedPAC stated that it is not clear how CMS is using calcimimetic expenditure data to estimate the CY 2020 MAP and FDL amounts. MedPAC noted that CMS has previously said that drugs eligible for the TDAPA (including calcimimetics) are not eligible for

outlier payments and that the 1 percent target for outlier payments is based on total ESRD PPS expenditures.

MedPAC stated that given that CMS has said that total ESRD expenditure amounts for 2020 include TDAPA expenditures for calcimimetics, they believe CMS proposed to target 1 percent of total expenditures, including TDAPA expenditures in 2020, when establishing the FDL amount. However, MedPAC noted, the outlier pool has been funded through a 1 percent reduction in the base rate (that was applied in 2011 and has remained in effect in each subsequent year by applying all annual updates to the reduced base rate) and therefore does not account for the TDAPA expenditures for calcimimetics, which are currently an add-on payment adjustment to the base rate. MedPAC stated that CMS has not proposed a budget-neutral method for funding the outlier policy in 2020 that accounts for the additional ESRD expenditures from add-on payment adjustments for calcimimetics under the TDAPA policy. MedPAC suggested that CMS should maintain a budget-neutral outlier policy either by excluding the TDAPA expenditures for calcimimetics from the total ESRD expenditures so that the 1 percent outlier payment target does not include the TDAPA expenditures (that is, the policy applied to the TDAPA payments for calcimimetics in 2018 and 2019), or by reducing the TDAPA expenditures by 1 percent so that funding for the outlier policy accounts for the TDAPA expenditures for calcimimetics. One national dialysis association expressed support for MedPAC's analysis, but did not support MedPAC's alternative recommendation that CMS consider reducing the TDAPA payments by 1 percent so that funding for the outlier policy accounts for the TDAPA expenditures for calcimimetics.

Several commenters expressed concern that CMS has proposed to include the TDAPA costs for calcimimetics in the outlier calculation, even though the drugs eligible for the TDAPA are not eligible for an outlier payment. A national dialysis stakeholder organization noted that while the statute requires CMS to include as part of the single payment amount for the ESRD PPS a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, it does not provide specifics as to how the outlier pool is determined or paid out. The organization acknowledged CMS's position that the TDAPA is part of the ESRD PPS single payment amount but expressed concerned that the calcimimetics should be included in the outlier pool. The organization noted that the CY 2020 ESRD PPS proposed rule estimated that more than $21 per treatment is removed from the base rate by including these drugs in the outlier calculations; yet, there is no ability to recover the dollars and they are permanently removed from the program. The organizations further commented that Congress established an outlier pool so that ESRD facilities treating extraordinarily costly patient are not disincentivized from doing so, but interpreting the statute to incorporate an add-on payment adjustment into the outlier calculation is inconsistent with this intent.

Another LDO and a national dialysis association expressed concern with CMS' proposal to include TDAPA spending on calcimimetics in the outlier pool for CY 2020. They stated that they see no justification in the rule for CMS to significantly increase the outlier target for CY 2020 by including calcimimetics when it is not statutorily required to do so and when the outlier target has not been achieved under the ESRD PPS in any year since implementation. The commenters stated that this has a decreasing effect on the base rate while increasing the likelihood that CMS will not actually spend these additional dollars on high cost cases, given that calcimimetics do not even qualify for outlier payments in CY 2020. They further stated that it seems incongruous to include calcimimetics expenditures in the outlier pool, given what they called the separate treatment of calcimimetics outside the base rate under the TDAPA and the fact that, under Medicare regulations, these drugs do not qualify toward the outlier calculation while they are eligible for the TDAPA. They recommended that rather than increasing the amount of funding withheld from providers that they are unlikely to see in outlier payments, CMS should exclude calcimimetics (which are not eligible for outlier payment during the TDAPA) from the target percentage for CY 2020.

One national dialysis association opposed CMS' methodology described in the proposed rule to include the TDAPA expenditures for calcimimetics in the calculation for the outlier pool, noting that CMS proposed to add more than $21 per treatment to the ESRD PPS base rate and then withhold 1 percent of this for the outlier pool. They stated this will result in CMS withholding an even greater amount of dollars from the ESRD PPS that, based on the long history of poor performance in the outlier pool, will not be repaid to facilities. The association stated that CMS's proposal is particularly concerning because drugs paid through the TDAPA (including calcimimetics) and devices paid through the proposed TPNIES are not eligible for the outlier pool. Therefore, the association stated, any increase in the withhold for the outlier pool as a result of the TDAPA and the proposed TPNIES will have no correlation to utilization of the outlier pool. The association objected to CMS increasing the withhold for the outlier pool knowing that the withheld dollars will not be returned to the system for patient care.

The association does not believe that CMS should finalize the proposed outlier methodologies that would include expenditures for the TDAPA or the proposed TPNIES in the outlier calculation. The association stated that CMS has sufficient statutory authority to exclude both the TDAPA and the proposed TPNIES from the outlier pool calculation and should do so in the final rule for CY 2020 and beyond. The association noted that there is no statutory requirement that the outlier pool include the ESRD PPS base rate plus the TDAPA or TPNIES. Nor does the ESRD PPS statute require the outlier pool to be based on the total payments made under the ESRD PPS.

Response: We recognize the confusion by the commenters regarding our discussion of calcimimetics and the outlier policy, and we would like to clarify we did not propose any changes to the outlier policy methodology in the CY 2020 ESRD PPS proposed rule, nor did we make any changes to the methodology when calculating the FDL amounts published in the CY 2020 ESRD PPS proposed rule. The projected total ESRD PPS outlier payment for CY 2020 is 1 percent of the sum of ESRD PPS base rate expenditures and TDAPA expenditures. We acknowledge that including the TDAPA expenditures in this calculation results in a larger than expected outlier payment compared to a scenario in which these TDAPA expenditures are not included. However, the TDAPA is a part of the ESRD PPS, and expenditures for the TDAPA are ESRD PPS expenditures. Because of this, these amounts are used when updating the outlier thresholds. We also note that other renal dialysis items and services, such as composite rate items and services, are not eligible outlier services but their expenditures are included in the overall ESRD PPS expenditures and are therefore taken into account when calculating the FDL amounts. We will take these concerns into consideration for future rulemaking.

Comment: An LDO expressed concern about extending outlier payment eligibility subsequent to applying a TDAPA or TPNIES as the sole payment mechanism for new treatments. They noted that CMS has recognized that outlier payments address ''unusual variations in the type or amount of medically necessary care'' related to patient conditions such as frailty, obesity, and comorbidities, such as cancer. The LDO asserted that using the outlier pool in this manner goes beyond its intent and design, and will always lead to lower reimbursement relative to the TDAPA and TPINES. The LDO stated that there is no guarantee that a facility would receive any payment for the new treatment. The LDO suggested that an ESRD facility would at best receive the equivalent of ASP–20 percent less the sequestration's impact for a drug or biological product. The LDO stated that any relief under this policy would likely be further compromised by the lack of outlier payment pool parity.

Some commenters also suggested that CMS adjust the outlier percentage to more accurately represent the percentage of total payments that have been historically paid under the outlier policy or otherwise address what appears to be weakness in CMS' approach. Finally, they recommended that CMS establish a mechanism in the ESRD PPS to return unpaid amounts withheld from providers as part of the target percentage when it does not achieve the 1 percent outlier policy in a given year.

Response: We appreciate the commenters' concerns regarding the incorporation of TDAPA or TPNIES products into the outlier policy after the respective add-on payment adjustments end. As we have stated in the TDAPA and TPNIES sections above, these add-on payment adjustment are to support the ESRD facilities in the uptake of new and innovative drugs and biological products and equipment and supplies. We believe that once these products complete the TDAPA or TPNIES period that they compete in the outlier space. However, we note that the TEP will address the outlier policy as part of its efforts to refine the ESRD PPS. In addition, we will take these concerns into consideration for future rulemaking.

Comment: A physician association commented on the proposed pediatric adjustment for outlier payments of 8.2 percent. The association noted that the pediatric outlier amount is decreasing as a result of a decrease in utilization of these services in the pediatric population. The association expressed concern that the outlier calculation does not currently capture all of the services pediatric ESRD patients require, including management of co-morbidities seen in many pediatric dialysis patients such as failure to thrive and seizure disorder. Additional unique costs are for care coordination, as the pediatric dialysis unit frequently functions as the child's medical home. The association stated that CMS should ensure that the pediatric outlier policy recognizes conditions and services unique to the pediatric population, and requested that CMS examine the accuracy of its data in capturing pediatric co-morbidities before implementing any cuts to the pediatric outlier services. The association also noted that any pediatric modifiers should be based on actual cost data from pediatric dialysis facilities for recent years. Without adjustments based on accurate cost data, the association maintained, the long-term economic viability of pediatric dialysis units will be jeopardized, and adult units will be further disincentivized to meet the special needs of their pediatric patients who are unable to access specialized pediatric dialysis units.

Response: We note that outlier payments are based on services billed on claims. As a result, the pediatric thresholds are based upon reported data. In addition, the reduction to the FDL amount reflects that outlier payments did not reach the 1 percent target percentage. When that occurs, the FDL amount is lowered so that more claims qualify for outlier payment so that 1 percent of total ESRD PPS payments are outlier payments. In response to the physician association's suggestion that we capture all of the services pediatric ESRD patients require, including management of comorbidities seen in many pediatric dialysis patients such as failure to thrive and seizure disorder, we intend to address data issues through the next TEP meeting which will inform the next refinement of the ESRD PPS.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2020 displayed in Column II of Table 2 of this final rule and based on CY 2018 data.

d. Final Impacts to the CY 2020 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the per-treatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, and the TDAPA (as finalized in section II.B.1.e of this final rule). Beginning in CY 2020 the per-treatment payment amount also will be adjusted for any applicable TPNIES (as finalized in section II.B.3.b.iii of this final rule).

ii. Annual Payment Rate Update for CY 2020

The ESRD PPS base rate for CY 2020 is $239.33. This update reflects several factors, described in more detail as follows:

- *Market Basket Increase:* Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2020 projection for the final ESRDB market basket is 2.0 percent. In CY 2020, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously, the final MFP adjustment for CY 2020 is 0.3 percent, thus yielding a final update to the base rate of 1.7 percent for CY 2020. Therefore, the ESRD PPS base rate for CY 2020 before application of the wage index budget-neutrality adjustment factor would be $239.27 ($235.27 × 1.017 = $239.27).
- *Wage Index Budget-Neutrality Adjustment Factor:* We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2020, we did not

propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 2020 wage index budget-neutrality adjustment factor using treatment counts from the 2018 claims and facility-specific CY 2019 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2019. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2020. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2020. The total of these payments became the new CY 2020 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2020 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2020 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates.

The final CY 2020 wage index budget-neutrality adjustment factor is 1.000244, based on the updated wage index data. This application would yield a final CY 2020 ESRD PPS base rate of $239.33 ($239.27 × 1.000244 = $239.33).

The comments and our responses to the comments on our proposals to update the ESRD PPS base rate for CY 2020 are set forth below.

Comment: A professional association expressed appreciation for the proposed increase to the ESRD PPS base rate for CY 2020, but noted that the proposed amount will not fully cover costs associated with providing high-quality care to patients, particularly by small and independent providers with limited resources offering care in many cases to patients in rural and underserved areas where access challenges may be present. The commenter stated that the proposed payment increase will not sufficiently cover the annual growth in costs for ESRD facilities necessary to offer high-quality care to pediatric and adult ESRD patients. Particularly with respect to the provision of home dialysis, the association underscored that only 2 vendors currently offer home dialysis equipment and supplies. They further stated that the home dialysis equipment and supplies have increased in cost by 20 percent to 30 percent. The commenter asserted that the ESRD PPS does not reflect these significant cost increases in home dialysis equipment and supplies. The association noted that MedPAC reported an overall −1.1 percent Medicare margin for ESRD facilities in its 2019 March Report to Congress, including a −5.5 percent margin for rural facilities and a −21.3 percent margin for facilities in the lowest quintile by volume.

Response: We appreciate these comments. As we stated in section II.B.3.d.i of this final rule, we established an ESRD PPS base rate that reflected the lowest per patient utilization data as required by statute. This amount is adjusted for patient specific case-mix adjustments, applicable facility adjustments, and geographic difference in area wage levels which are reflective of facility costs since cost data is used to derive the adjustment factors. The CY 2016 ESRD PPS final rule discusses the methodology for calculating the patient and facility-level adjustments (80 FR 68972 through 69004). In addition, the ESRD PPS base rate is adjusted for any applicable outlier payment, training add-on payment, and the TDAPA to arrive at the per treatment payment amount. The ESRD PPS base rate is annually updated by the ESRDB market basket and adjusted for productivity and wage index budget neutrality.

For these reasons, we believe that the CY 2020 ESRD PPS base rate is appropriate despite the challenges some ESRD facilities experience. We also continue to believe that the payment adjustments help mitigate the challenges faced by those facilities that are eligible for the adjustments. We note that the ESRDB market basket for CYs 2015 through 2018 was reduced in accordance with section 217(b)(2) of PAMA but for CY 2019 and CY 2020, ESRD facilities are getting the full productivity-adjusted ESRDB market basket update, which results in increased per treatment payments.

Final Rule Action: We are finalizing a CY 2020 ESRD PPS base rate of $239.33.

C. Miscellaneous Comments

We received many comments from beneficiaries, physicians, professional organizations, renal organizations, and manufacturers related to issues that were not the subject of proposals and therefore, were out of scope of the CY 2020 ESRD PPS proposed rule. These comments and our responses are summarized below:

Comment: MedPAC noted that PAMA required that the Secretary conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services, consistent with a prior MedPAC recommendation. MedPAC noted that in September 2015, CMS awarded a contract to conduct the audit. MedPAC requested that CMS release the final results of the audit.

MedPAC noted that in the CY 2019 ESRD PPS final rule, CMS said that the audit process is complete and the audit staff are reviewing the findings. MedPAC emphasized the importance of auditing the cost reports that ESRD facilities submit to CMS to ensure that the data are accurate. First, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors and ESRD market basket index, which are derived from this data source. Second, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. MedPAC noted that if costs are overstated, then the Medicare margin is understated. Third, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Fourth, historically, facilities' cost reports have included costs that Medicare does not allow.

Response: We appreciate MedPAC's thoughts and suggestions on our cost reports and audits. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56973), the audit process is complete. CMS is conducting follow-up activities related to the audit to obtain summary results and investigating what adjustments were made on the cost reports of specific ESRD facilities. We will discuss the results when these follow-up activities are available in a future rule.

Comment: A professional association suggested that CMS implement changes to Medicare cost reports, claims, and Explanation of Benefits (EOB) forms to allow for separate identification, coding, and reimbursement of the TDAPA-eligible products so that providers and CMS can more easily track use of and spending on these therapies. The professional association stated that currently, many facilities do not have a clear understanding of how much reimbursement they receive specifically for each calcimimetic claim because the Medicare EOBs do not separate out calcimimetic reimbursement. To remedy this, the professional association

recommended that Medicare EOBs should reflect separately all procedures, pharmaceutical products, laboratory tests, etc. so that these items are able to receive separate reimbursement and able to be appropriately tracked and reported on CMS Provider Statistical & Reimbursement Reports and facility cost reports.

Responses: We appreciate the commenter's suggestion for transparency of payment directly related to the TDAPA. While this add-on payment adjustment is one component of the ESRD PPS payment amount as described in the newly revised § 413.230, in Change Request 10065,[35] we included instruction for the contractors to capture the payment amount directly related to the TDAPA and make this information available in reports. Therefore the CMS Provider Statistical & Reimbursement Report is capturing this value.

Comments: Several commenters suggested refinements to the ESRD PPS with regard to the case-mix adjusters. A patient advocacy organization requested that CMS ensure the patient case mix adjusters are serving their intended purpose. The organization is concerned that using cost reports as the data source for the age, weight, BSA, and BMI case mix adjusters are neither reliable nor reflecting the patient characteristics that clinicians believe are drivers of higher costs. The organization stated that it agrees with MedPAC and supports the elimination of the co-morbid case-mix adjusters for pericarditis, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome. The organization noted that the documentation of these conditions can be burdensome, and it has found limited benefit to the use of information collected. The organization stated that misaligned payment adjusters can negatively impact a facility's ability to provide individualized high-quality care to pediatric and adult ESRD patients, and this is concerning, as it creates greater financial risk for ESRD facilities, particularly for small and independent facilities with limited resources, that are bearing financially burdensome costs for costly patients. The organization stated that returning the funding to the ESRD PPS base rate will benefit patient care. The organization urged CMS to eliminate comorbidity adjustments from the payment system until the agency develops appropriate adjusters that accurately capture variance in costs of care for particularly high-cost, high-acuity patients, and work quickly with clinicians to revise the patient adjusters to ensure they serve their purpose of accounting for higher cost patients.

An LDO commented on the shortcomings of the case-mix adjusters. The LDO provided a detailed analysis of internal treatment run time data, showing that costs comprising nearly 40 percent of the market basket rate, wages, salaries, and benefits, had virtually no correlation to age. The LDO stated that it focused on these costs because there is no patient-level variation in housekeeping and operations, administration, and capital expenses, and thus no age correlation. Although costs for pharmaceuticals and laboratory services do vary minimally by patient, their correlation to age is ambiguous due to confounding with the BSA, BMI, and outlier adjustments. Given the consistency in treatment run times across age groups, the LDO noted that it was difficult to understand the nearly 15 percent swing in relative costs between patients aged 45 to 59 and patients aged 70 to 79 under the 2011 and 2016 models. The LDO further noted that it, along with other members of the kidney care community, and MedPAC have consistently raised concerns about the use of facility cost report data in developing patient-level adjusters. The LDO stated that the mean treatment run time analysis may not be achieving the intended purpose.

A professional association noted that during the December 8, 2018 ESRD PPS Technical Expert Panel (TEP) meeting convened by CMS, the panelists shared the same concerns as the LDO about alignment of resource use with payment with regard to patient-level adjusters.. The association stated that even when pressed to try to identify additional new adjusters, the vast majority indicated that very few adjusters are truly necessary for the ESRD population.

Some commenters noted concern with the low-volume and rural adjustments, and referenced MedPAC's concern about the overlapping nature of the low-volume and rural adjusters in its most recent Commission meetings. Commenters described MedPAC's April 2019 meeting, in which the staff presented an example of a single low-volume and isolated (LVI) facility adjuster that would better target payments. Some professional associations stated that they conceptually support such an approach. The structure of the low-volume payment adjustment (LVPA) and rural payment adjuster resulted in more than 50 percent of ESRD facilities that received the LVPA also claiming the rural adjuster. Commenters noted that MedPAC's analysis to date supports a conclusion that these adjusters have not led to an efficient distribution of resources or had much impact in improving a low-volume or rural ESRD facility's financial position. An LDO said CMS should explore modifying the low-volume and rural adjusters, such as creating a 2-tiered low-volume adjuster as MedPAC has discussed, and by considering a rural ESRD facility's coverage mix. One healthcare provider urged CMS to consider additional ways to appropriately reimburse low volume, rural facilities. The healthcare provider noted CMS should be aware of several closures of small rural facilities in the Midwest and stated that these closures are directly related to operational losses sustained by the ESRD facilities over a period of several years. The healthcare provider urged CMS to evaluate the base rate and rural and low volume adjusters to ensure ESRD facilities are reimbursed at a rate that covers the cost of care in rural communities. The healthcare provider stated that appropriate reimbursement rates will allow facilities to maintain high quality care and maintain local access to dialysis services.

A national dialysis stakeholder organization commented on the overall underfunding of ESRD facilities due to patient-level, facility level, add-on payment and outlier adjustments. The organization asserted that the application of these current policies results in the actual dollars CMS pays out for ESRD care to be significantly less than what the Congress had indicated it should be. The organization stated that while sequestration continues to be a driving source of underpayments, the underpayment amount attributable to other factors, which are due to a mismatch among adjusters frequencies assumed by the standardization factor compared to actual payment increased substantially in 2018, remains high. The organization noted that estimations indicate that, taken together, the total underpayment for the PPS per treatment in 2018 was $11.11. The organization further stated that the underpayment due to the outlier pool was $1.54 per treatment. Sequestration accounted for $4.45 per treatment, with the ESRD QIP taking out 25 cents per treatment. The organization stated that the remainder of the underpayment appears to be due to the fact that CMS has incorporated the expenditures for calcimimetics into the outlier pool calculation. The commenter strongly objected to this inclusion. The commenter stated that given the

[35] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018-Transmittals-Items/R1999OTN.html?DLPage=1&DLEntries=10&DLFilter=10065&DLSort=1&DLSortDir=ascending.*

negative margins, each dollar that comes out of the program reduced the funding available to support patient care and innovation.

Response: We appreciate the concerns raised by stakeholders regarding the technical nature of the ESRD PPS model. We intend to address these issues through the next TEP meeting which will inform the next refinement of the ESRD PPS. We will also consider these concerns for future rulemaking.

Comment: An LDO expressed appreciation for CMS' response to comments on the CY 2019 ESRD PPS proposed rule regarding the challenges ESRD facilities encounter when trying to obtain information on a patient's comorbid conditions. The LDO agreed that this information is important in developing comprehensive, effective treatment plans. The LDO also agreed that collecting these data should not be burdensome or cumbersome for ESRD facilities, but stated that it is finding it particularly difficult to get these data when a patient overwhelmed by a health crisis that requires a hospitalization forgets to provide necessary contact information. In these situations, despite several attempts, the LDO states that it frequently cannot obtain discharge instructions/summaries, pending laboratory results, and other relevant information on its patients' behalf. The LDO noted that this lack of communication complicates dialysis providers' ability to submit documentation necessary to receive comorbidity adjustments, which when left unclaimed lead to inappropriate reductions in ESRD PPS payments. The LDO disagreed with CMS's suggestion that in the absence of data necessary to receive a comorbidity adjustment, receiving funds through the outlier pool is an acceptable alternative.

The LDO suggested that, rather than a work-around through the outlier policy, CMS should take steps to ensure that the comorbidity adjusters perform as intended. The LDO stated that without an explicit requirement to do so, some providers rarely, if ever, make the necessary information available to ESRD facilities. The LDO recommended that CMS should require hospitals, particularly those using certified health information technology, to send the following information to other providers involved in an ESRD patient's care: (1) Discharge instructions and discharge summary within 48 hours; (2) pending test results within 72 hours of their availability; and (3) all other necessary information specified in the ''transfer to another facility'' requirements.

Response: We appreciate the LDO's concerns regarding the difficulties of obtaining documentation. We note that the agency has addressed this concern in the final rule entitled, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51836).[36]

Comments: Two commenters noted that unrecovered bad debt cuts into reimbursement. One professional association suggested that we make the TDAPA-eligible products eligible for bad debt reimbursement. The commenter stated that the TDAPA-eligible products are expensive for both the ESRD facilities that administer them and the Medicare beneficiaries who pay 20 percent co-insurance with their use. Small and independent facilities with limited resources face especially significant challenges in providing the TDAPA-eligible products to patients when they risk not receiving full payment, inclusive of beneficiary cost-sharing, for the costs associated with acquiring, storing, and administering these therapies. The association emphasized that all ESRD Medicare beneficiaries should have access to the medications they need to treat their ESRD-related medical conditions to improve or maintain their health and prevent hospitalizations or other costly therapies and interventions without concern for their affordability.

Several commenters provided suggestions on the incorporation of calcimimetics into the ESRD PPS base rate. Commenters urged CMS to work with stakeholders when developing a mechanism that does not result in facilities that provide the drugs used by only a small percentage of dialysis patients do so at a significant loss, while facilities that do not provide these drugs receive additional payments because the amount added to the base rate is distributed evenly across all payments. Commenters requested that before CMS incorporates costs for these drugs into the ESRD PPS base rate, it consider how their limited utilization will impact the distribution of dollars that will be added.

One drug manufacturer suggested that CMS should have the option to lengthen the duration of the TDAPA payment period for new renal dialysis drugs and biological products in existing ESRD PPS functional categories beyond 2 years, and use the language ''at least 2 years'' for these products similar to the language for products in new ESRD PPS functional categories. An LDO and a national dialysis association commented that CMS should ensure accurate expense accounting by including the ESRD network fee on cost reports. The association noted that the composite rate has been replaced by the ESRD PPS, but the 50 cents reduction has remained intact. The commenters noted that when Congress first created the ESRD Networks in 1978, the programs were funded through the appropriations process, with the goal of establishing funding for the programs through a network fee that reduced payments to dialysis facilities was to ensure stable funding for these programs. They noted that the history is silent as to whether this ESRD network fee should be accounted for on the ESRD cost reports. The association recommended CMS account for the ESRD network fee as a ''revenue reduction'' on the Cost Report. This addition could influence policymakers to increase the payment rate over time, better aligning cost reporting with the basis of payment. However, they do not think adding this information will affect the payment rate directly. They noted that since Medicare based rates on total historic payments, then use of actual historic payments means the reduction has already been included in its data. The association maintained that the cost reports (1) have not been used in calculating payment rates in a way that would affect the payment rates, and (2) have been used in the regression analysis to estimate adjuster values, but this change should not affect these analyses as the revenue reductions do not vary with any patient, facility or modality characteristic.

A dialysis organization encouraged CMS to include the $0.50 ESRD network fee in dialysis facilities' cost reports, noting that the fee's exclusion understated facilities' costs by more than $20 million in 2017. The organization asserted that since neither the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), which established the network fee, nor accompanying House report address the fee's inclusion or exclusion, CMS has the necessary authority to implement this policy change, and the organization encouraged CMS to explore other policy guidance avenues to add the network fee as a revenue reduction on Worksheet D effective with CY 2020 ESRD facility cost reports.

Two LDOs and a national dialysis organization requested CMS change its TDAPA billing guidance for ESRD facilities to report oral drugs on a claim

[36] *https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals.*

from the amount consumed (or amount according to the plan of care) to the amount dispensed. The LDO stated that documenting the amount consumed is overly burdensome and creates a significant challenge to dialysis providers, and ultimately cannot be proven for medications taken by patients at home.

The commenters noted that this creates a significant challenge for ESRD facilities. Over the course of a treatment, a lower or higher dose than initially recommended may be needed due to changes in a patient's condition. Other practical matters, such as a patient's relocation that necessitates the delivery of services at a different, geographically closer facility, make the requirement even more complicated and impractical. The commenters noted that the policy leads to losses for facilities that are not incurred by other provider types or Part D pharmacies and also makes facilities unfairly financially responsible for the entire amount dispensed. For oral drugs delivered through the ESRD PPS, the commenters stated, there is a disconnect between oral drugs prescribed for daily use, including days that do not include a dialysis treatment, and the ''per treatment'' payment methodology. This disconnect can result in ESRD facilities being unable to report oral drug utilization on days without a dialysis treatment. The commenters noted that current CMS policies require providers to attest in good faith on claims the amount of certain oral drugs consumed by beneficiaries, but this is not possible for dialysis providers, who cannot track beneficiary conduct in their homes on non-treatment days. The commenters therefore urged CMS to allow the reporting of the amount of dispensed but not consumed by beneficiaries as a more accurate and fair representation of what is under the control of the facility.

The commenters stated that this change would align the reporting requirement with those applied to other sectors including a skilled nursing facility (SNF) providing immunosuppressants and a hospital outpatient department providing patients with more than a 1-day supply of an anti-cancer drug. The commenters maintained that this modification also would ensure that CMS remains neutral with respect to providers' prescribing decisions and that patients have good access to the formulation that best meets their clinical needs. They also suggested that CMS provide guidance and appropriate reimbursement for a pharmaceutical product that must be discarded due to patient death, prescription change, facility transfer, hospitalization, transplantation or other circumstances that are outside the control of the ESRD facility. The commenters suggested that CMS provide guidance for product that, despite best efforts, has been lost in delivery, or misplaced by the beneficiary, and allow the facility to submit, and be reimbursed for, the second supply, perhaps through use of a modifier or similar system.

One national dialysis stakeholder organization and 1 drug manufacturer urged CMS in the coming year to work with the industry to find a better price proxy for non-ESAs that are not over the counter (OTC) vitamins. Specifically, they recommended that CMS use the BLS Series ID: WPS063 Series Title: PPI Commodity data for Chemicals and allied products—Drugs and pharmaceuticals, seasonally adjusted. They noted that the current category references ''vitamins,'' in a way that does not appropriately capture the price of drugs that fall within this category. Currently, the drugs in this category represent a small portion of the overall cost of providing dialysis services; however, the need for a more accurate and appropriate price proxy for oral and non-ESA drugs should be addressed now. Vitamin D analogs in this category, such as doxercalciferol and paricalcitol, are synthesized hormones that suppress PTH without inducing severe hypercalcemia, distinguishing them from OTC vitamins. They stated that these products are all unique chemical entities, FDA-approved, available by prescription only, and indicated for the treatment of secondary hyperparathyroidism (SHPT) which contributes to the development of bone disease. Moreover, these prescription drugs are classified by the U.S. Pharmacopeia in the Medicare Model Guidelines, a classification system that supports drug formulary development by Medicare Part D prescription drug plans, as ''Metabolic Bone Disease Agents,'' not vitamins.

The commenters stated that the creation of the TDAPA for new renal dialysis drugs and biological products will likely result in a shift in drug mix within the bundle, as well as introduce new oral products that deserve an accurate price proxy for updating. They noted that there are new drugs in the pipeline currently that, if the ESRD PPS does not create disincentives for their continued development, will likely be added to the ESRD PPS bundled payment during the next 2 to 3 years. The association recommended that CMS establish an alternative price proxy for these other drugs that is based on prescription drugs rather than vitamins and that would include fewer OTC drugs.

A drug manufacturer asked CMS to clarify how it will evaluate new products to determine whether they will fall within the definition of a ''renal dialysis service.''

An LDO commented that the absence of adequate and sustained payments in the ESRD PPS bundled payment for new treatments will not just affect ESRD beneficiaries in Medicare FFS, but will also flow into, and lower, Medicare Advantage (MA) ESRD payments. The LDO urged CMS to consider this impact and how it will affect ESRD beneficiaries, who will have the opportunity starting in 2021 to enroll in an MA plan just like other beneficiaries.

A physician association stated that it continued to have significant concerns about the pediatric case mix adjuster and the undervaluation of pediatric ESRD supplies and services. The association noted that it has previously requested that CMS evaluate pediatric facility Medicare cost reports and ensure that the Medicare claims forms and CROWNWeb data accurately reflect what is required to deliver quality care to pediatric patients. The association stated that the data CMS is using fail to reflect the necessary resources and associated costs of delivering pediatric ESRD care. In particular, the association stated that there is not a good mechanism to report some of the costs uniquely associated with pediatric patients, such as costs associated with the allied health team. The association recommended that CMS look beyond the currently required report data and consider what expenses unique to pediatric dialysis should be included to appropriately reflect the costs of pediatric ESRD care, and to improve the completeness and accuracy of pediatric data being reported.

The association listed certain unique expenses related to pediatric dialysis care that should be reflected in any pediatric ESRD facility payment formula, including: (1) Increased reliance on registered nurses to provide dialysis care; (2) developmental/behavioral specialists; (3) more frequent assessment by pediatric dieticians; (4) social workers, teachers, and designated liaisons to interface regularly with schools; and, (5) a broad array of dialysis supplies.

The commenter noted that without accurate reimbursement to pediatric facilities, those who are specially trained to care for this unique patient population, as well as pediatric ESRD patients themselves, face an uncertain future. The commenter stated there is already a shortage of pediatric

nephrologists and inadequate reimbursement will further exacerbate this shortage and result in limited access of pediatric dialysis patients to specialized facilities with pediatric personnel trained to care for their unique needs. The commenter noted that the result will likely be worse health outcomes for children with ESRD, with the potential for higher costs of care when these children mature to adulthood. The commenter stated that the ultimate goal should be to ensure that reimbursement is appropriate so that pediatric facilities and providers can continue to provide high quality services to those in need.

Response: We appreciate receiving these comments regarding issues affecting ESRD facilities and beneficiaries. However, we did not include any proposals regarding these topics in the CY 2020 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule. We will consider these comments and issues when developing ESRD PPS policies in the future.

III. CY 2020 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by an ESRD facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2020 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 38330 through 38421), hereinafter referred to as the ''CY 2020 ESRD PPS proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that proposed rule, we proposed to update the AKI dialysis payment rate. We received approximately 4 public comments on our proposal, including comments from ESRD facilities; national renal groups, transplant organizations; and nurses.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2020 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2020

1. CY 2020 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including market basket adjustments, wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.5.d of the CY 2020 ESRD PPS proposed rule (84 FR 38362), the CY 2020 proposed ESRD PPS base rate was $240.27, which reflected the proposed market basket, multifactor productivity adjustment, and CY 2020 wage index budget-neutrality adjustment factor. Therefore, we proposed a CY 2020 per treatment payment rate of $240.27 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.5.b of the CY 2020 ESRD PPS proposed rule (84 FR 38359 through 38360). The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We proposed a CY 2020 AKI dialysis payment rate of $240.27, adjusted by the ESRD facility's wage index.

The comments and our responses to the comments regarding the AKI dialysis payment proposal are set forth below.

Comment: Some commenters noted that they support the proposed AKI payment rate for CY 2020. They noted that in the CY 2017 ESRD PPS final rule, CMS announced that it would be developing a formal monitoring program for AKI dialysis payments, but the specifics have yet to be published. They said they would also find it helpful to

understand how CMS is monitoring the AKI benefit. They stated their support for CMS's plan to develop a program to monitor utilization of dialysis and all separately billable items and services furnished to beneficiaries with AKI. They reiterated their interest in maintaining a dialogue as part of this monitoring program to ensure that the payments for AKI patients are adequate and stated that it may be necessary for CMS to establish an ''AKI adjustment'' to the payment rate to address the differences in the services provided to AKI patients from those provided to ESRD patients. They encouraged CMS to make the AKI benefit's monitoring plan and any insight obtained to date available to stakeholders, noting that transparency regarding this information is crucial to supporting our shared objectives of ensuring AKI payment adequacy.

Response: We thank the commenters for their support of the AKI payment rate. We are in the process of evaluating the methodology to be used for determining significant differences in resource use with AKI patients in contrast to ESRD patients. We have met with dialysis center physicians affiliated with academic medical centers to discuss differences in care requirements for the AKI patient and the ESRD patient. The stated that they separate their AKI patients from their ESRD patients and monitor their treatment, recovery, or progression to ESRD. Along with our in-house medical officers, our data contractor employs 2 nephrologists with whom we are consulting on differences in treatment of AKI patients and ESRD patients in order to evaluate resource use and a potential AKI adjustment. Such resource use would include time on dialysis machine, frequency of dialysis, drug requirements and lab tests, treatment protocols and additional practitioner time to evaluate medical status. In addition, CMS has an ESRD monitoring and evaluation team in the Centers for Clinical Standards and Quality clinical monitoring, that regularly discusses the monitoring of ESRD beneficiaries. We continue to be interested in feedback and data from the public regarding AKI patients and we intend to continue researching these issues and potentially addressing them through rulemaking and other mechanisms in the future.

Comment: One nursing association emphasized the critical role of nephrology nurses and the increased responsibilities that are placed on them when managing the complex nursing and care needs of patients with AKI. The association stated that the unique and distinct characteristics of the ESRD and AKI patient populations require critical differences in treatment protocols. The association noted that AKI patients require more vigilant monitoring, particularly in infection prevention, blood pressure management, more frequent laboratory testing, additional medication administration, and increased educational needs. The care of an AKI patient often requires more care coordination of the interdisciplinary team. The association stated that these are not patient care responsibilities that can be delegated to technicians or other staff; only specialized nephrology nurses can provide the type of highly intensive and coordinated care that is necessary for these patients to achieve improved health outcomes. Given the increased nursing time required to provide high-quality care to AKI patients, the commenter urged CMS to recognize the specialized high-quality nursing care that nephrology nurses offer as CMS considers modifications to the AKI payment policy.

Response: We thank the commenter for noting the differences such as increased monitoring of signs for infection, infection prevention, blood pressure management, more frequent laboratory testing and increased nursing time in the AKI patients. As we noted previously, we are aware of these differences and would encourage the association to continue to share information with us as we evaluate the differences in resource use of the ESRD and AKI patient. We will take all the cited examples into consideration for AKI monitoring and for future rulemaking.

Comment: One commenter suggested that AKI payments be competitive with ESRD PPS payments. The commenter noted that transplant recipients often have AKI early after transplant surgery and require dialysis support until transplant function is established. The commenter stated that currently, outpatient dialysis centers can receive payment for patients that are dialyzed for the diagnosis of AKI, however, most centers are not dialyzing these patients. The commenter stated that it suspects this is because the ESRD facilities do not want to give up a chronic spot to an acute patient that may only require treatment for a limited time. The commenter stated that the chronic ESRD patient is a guaranteed bundled payment patient. Physicians typically see the AKI patient weekly for 4 weeks. The commenter stated that if a patient is only in the unit 1 week as an acute patient, the reimbursement is much less and therefore, the units tend to not want these patients in the chronic chairs.

Response: We thank the commenter for sharing this insight into the post-transplant scenario when it involves AKI patients. The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including market basket adjustments, wage adjustments and any other discretionary adjustments, for such year.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2020 ESRD PPS base rate is $239.33. Accordingly, we are finalizing a CY 2020 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as $239.33.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules: 75 FR 49030, 76 FR 628, 76 FR 70228, 77 FR 67450, 78 FR 72156, 79 FR 66120, 80 FR 68968, 81 FR 77834, 82 FR 50738, and 83FR 56922. We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Finalized Policies for the ESRD QIP

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 38330 through 38421), hereinafter referred to as the ''CY 2020 ESRD PPS proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that rule, for the ESRD QIP, we proposed updates to the ESRD QIP, including for PY 2022 and

PY 2023. We received approximately 29 public comments on our proposal, including comments from large dialysis organizations, renal dialysis facilities, national renal groups, nephrologists, patient organizations, patients and care partners, health care systems; nurses, and other stakeholders. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ESRD QIP.

The comments and our responses to the comments on the ESRD QIP are set forth below.

Comment: Commenters provided feedback on adding new measures to the ESRD QIP. Commenters' suggestions for new measures included NQF-endorsed measures of dialysis adequacy, different Kt/V measures for different dialysis patient demographics, an NQF-endorsed alternative to the ESRD QIP's Ultrafiltration reporting measure, and a depression measure specific to the ESRD community.

Response: We thank the commenters for their recommendations and welcome feedback on ways to improve the program, including the adoption of new or revised measures. However, we note that these comments are not responsive to a proposal included in the CY 2020 ESRD PPS proposed rule, and therefore, are considered beyond the scope of the CY 2020 ESRD PPS proposed rule. We refer readers to the CY 2019 ESRD PPS final rule (83 FR 56982 through 57016), CY 2018 ESRD PPS final rule (82 FR 50767 through 50769), the CY 2017 ESRD PPS final rule (81 FR 77898 through 77906) and the CY 2016 ESRD PPS final rule (80 FR 69052) for discussions of the measures that we have previously adopted for the ESRD QIP.

C. Updates to Regulation Text

We proposed to revise the requirements at § 413.178 by redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively. In addition, we proposed to add a new paragraph (d) to specify the data submission requirements for calculating measure scores. Specifically, we proposed to codify the requirement that facilities must submit measure data to CMS on all measures. We stated that this proposed regulation text would codify previously finalized policies and would make it easier for the public to locate and understand the Program's quality data submission requirements.

Additionally, we stated that the proposed text in new paragraph (d)(2) would codify our proposed policy (discussed more fully in section IV.E.2 of this final rule) to adopt the performance period and baseline period for each payment year automatically by advancing 1 year from the previous payment year. At § 413.178(d)(3) through (d)(7), we proposed to codify requirements for the Extraordinary Circumstances Exception (ECE) process, including a new option for facilities to reject an extraordinary circumstance exception granted by CMS under certain circumstances. We stated that this new option would provide facilities with flexibility under the ECE process. We also proposed this provision to provide clear guidance to the public on the scope of our ECE process. We invited public comments on these proposals.

The comments and our responses regarding the proposed regulation text are set forth below.

Comment: Commenter expressed support for the proposal to codify the requirement that facilities must submit measure data to CMS on all measures. Commenter noted its appreciation of the predictability that will result from CMS codifying its previously finalized policies.

Response: We appreciate and thank the commenter for its support.

Comment: Commenters expressed support for CMS's proposal to codify its requirements for the ECE process, including a new option for facilities to reject an ECE granted by CMS under certain circumstances.

Response: We appreciate and thank the commenters for their support.

Final Rule Action: After consideration of the public comments we received, we are finalizing our proposed regulation text with one technical change. Section 413.178(d)(5) now clarifies that CMS will not consider an ECE request unless the facility making the request has complied with the requirements in § 413.178(d)(4).

D. Requirements Beginning With the PY 2022 ESRD QIP

The PY 2022 ESRD QIP measure set includes 14 measures, which are described in Table 3. For more information on these measures, including the two measures that are new beginning with PY 2022 (the Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure and the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure), please see the CY 2019 ESRD QIP final rule (83 FR 57003 through 57010).

TABLE 3—PY 2022 ESRD QIP MEASURE SET

NQF No.	Measure title and description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure.
	Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure.
	Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
2979	Standardized Transfusion Ratio (STrR), a reporting measure.[37]
	Risk-adjusted STrR for all adult Medicare dialysis patients.
	Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure.
	A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure.
	Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.

[37] We are finalizing in section IV.D.2.b of this final rule that beginning with the PY 2022 ESRD QIP, the STrR measure will be scored as a reporting measure.

TABLE 3—PY 2022 ESRD QIP MEASURE SET—Continued

NQF No.	Measure title and description
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure. Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure. Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463*	Standardized Hospitalization Ratio (SHR), a clinical measure. Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate, a reporting measure. Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure. Number of months for which facility reports NHSN Dialysis Event data to CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure. Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure. Percentage of patient-months for which medication reconciliation was performance and documented by an eligible professional.

The comments and our response to the comments regarding our continuing measures are set forth below.

Comment: Commenters provided feedback on various aspects of measures that are continuing in PY 2022. These comments included recommendations to keep or remove continuing measures from the Program, recommendations to modify continuing measures (for example, by revising the Kt/V clinical measure's pooled approach in combining multiple dialysis patient populations into a single dialysis adequacy measure or by creating an additional exclusion for the PPPW clinical measure), and recommendations to change the ICH CAHPS survey to improve patients' response rates and reduce the associated provider burden by changing its administration. Commenters also urged CMS to be cognizant of the reporting burden imposed by quality measures and recommended aligning quality measures with other programs, using a single website to track and report performance data, and improving EHR data sharing.

Response: We thank the commenters for their recommendations and welcome feedback on ways to improve the program, including the adoption of new or revised measures. However, we note that these comments are not responsive to a proposal included in the CY 2020 ESRD PPS proposed rule, and therefore, are considered beyond the scope of the proposed rule.

1. Performance Standards for the PY 2022 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2019 ESRD PPS final rule (83 FR 57010), we set the performance period for the PY 2022 ESRD QIP as CY 2020 and the baseline period as CY 2018. In the CY 2020 ESRD PPS proposed rule (84 FR 38364), we estimated the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2022 clinical measures using data from 2016 and 2017, as shown in Table 4. We also stated that we had proposed in the CY 2020 ESRD PPS proposed rule to convert the STrR measure from a clinical measure to a reporting measure and that if that proposal was finalized, we would not update these standards for the STrR measure.

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TABLE 4: Estimated Performance Standards for the PY 2022 ESRD QIP Clinical Measures

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type			
Standardized Fistula Rate	52.61%	63.69%	76.11%
Catheter Rate	18.24%	11.15%	5.02%
Kt/V Comprehensive	92.98% (92.75%)*	96.88% (96.83%)*	99.14% (99.10%)*
Hypercalcemia	1.81%	0.57%	0.00%
Standardized Readmission Ratio	1.268 (1.273)*	0.998	0.629 (0.642)*
Standardized Transfusion Ratio	1.684 (1.695)*	0.840	0.194
NHSN Bloodstream Infection	1.477	0.694 (0.698)*	0
Standardized Hospitalization Ratio	1.248	0.967 (0.971)*	0.670 (0.687)*
PPPW	8.75%	17.77%	34.29%
ICH CAHPS: Nephrologists' Communication and Caring	58.09%	67.81%	78.53%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16%	62.34%	72.03%
ICH CAHPS: Providing Information to Patients	73.90% (73.89%)*	80.38%	87.08%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.85%)*	62.22% (60.37%)*	76.57% (74.50%)*
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (49.10%)*	63.04% (63.03%)*	77.48%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.97%)*	67.93%	82.48% (82.34%)*
* If the PY 2022 final numerical value is worse than the PY 2021 finalized value, we will substitute the PY 2022 final numerical value for the PY 2021 finalized value. We have provided the PY 2021 finalized value as a reference for clinical measures whose PY 2022 estimated value is worse than the PY 2021 finalized value.			

Data sources: VAT measures: 2017 CROWNWeb; SRR, STrR, SHR: 2017 Medicare claims; Kt/V: 2017 CROWNWeb; Hypercalcemia: 2017 CROWNWeb; NHSN: 2017 CDC; ICH CAHPS: CMS 2017; PPPW: 2017 CROWNWeb and 2017 OPTN.

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We are now updating the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2022 clinical measures as shown in Table 5, using the most recently available data, which includes CY 2018 data.[38] As discussed more fully in section IV.D.2.b of this final rule, we are finalizing our proposal to convert the STrR measure from a clinical measure to a reporting measure. Accordingly, we did not include the STrR clinical measure in Table 5.

[38] In the CY 2020 ESRD PPS proposed rule (84 FR 38364), we inadvertently stated that the updated values would appear in the CY 2019 ESRD PPS final rule, instead of this final rule.

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TABLE 5: Finalized Performance Standards for the PY 2022 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)*	Median (50th Percentile of National Performance)*	Benchmark (90th Percentile of National Performance)*
Vascular Access Type			
Standardized Fistula Rate	52.52%	63.76%	76.16%
Catheter Rate	18.57%	11.22%	5.07%
Kt/V Comprehensive	93.10	97.04%	99.15%
Hypercalcemia	1.77%	0.58% (0.59%)	0.00%
Standardized Readmission Ratio	1.268 (1.269)	0.998	0.629 (0.641)
NHSN Bloodstream Infection	1.365	0.604	0
Standardized Hospitalization Ratio	1.248	0.967 (0.976)	0.670 (0.677)
PPPW	8.12%	16.73%	33.90%
ICH CAHPS: Nephrologists' Communication and Caring	58.12%	67.89%	78.52% (78.35%)
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16 (53.87%)	62.47%	72.11%
ICH CAHPS: Providing Information to Patients	74.09%	80.48%	87.14%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.92%)	62.22% (60.59%)	76.57% (75.16%)
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (48.59%)	63.04% (62.99%)	77.49%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.46%)	68.59%	83.03%
* If the PY 2022 final numerical value is worse than the PY 2021 finalized value, we will substitute the PY 2022 final numerical value for the PY 2021 finalized value. We have provided the PY 2021 finalized value as a reference in parentheses for clinical measures whose PY 2022 estimated value is worse than the PY 2021 finalized value.			

Data sources: VAT measures: 2018 CROWNWeb; SRR, SHR: 2018 Medicare claims; Kt/V: 2018 CROWNWeb; Hypercalcemia: 2018 CROWNWeb; NHSN: 2018 CDC; ICH CAHPS: CMS 2018; PPPW: 2018 CROWNWeb and 2018 OPTN.

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In addition, we have summarized in Table 6 our finalized performance standards for the reporting measures in the PY 2022 ESRD QIP.

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TABLE 6: Finalized Performance Standards for the PY 2022 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every HD Kt/V session during the week of the monthly Kt/V draw, and Kt/V date is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of BUN Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o ARNP, o PA, o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly data reported quarterly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
STrR		At least 10 patient-years at risk during the performance period.[39]

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[39] In section IV.D.2.b of this final rule we finalized a policy to convert the STrR measure from a clinical measure to a reporting measure.

2. Update to the Scoring Methodology Previously Finalized for the PY 2022 ESRD QIP

a. Update to the Scoring Methodology for the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

We stated in the CY 2020 ESRD PPS proposed rule that there were two similar measures in the ESRD QIP that assess dialysis events: (1) The National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, and (2) the NHSN Dialysis Event reporting measure. We stated that for the NHSN BSI clinical measure, facilities must be eligible to report 12 months of data to the NHSN on a

quarterly basis in order to receive a score on the measure, and are scored based on whether they submitted data for that 12-month period and how many dialysis events they reported during that 12-month period. We stated that for the NHSN Dialysis Event reporting measure, facilities must enroll in the NHSN, complete any required training, and report monthly dialysis event data on a quarterly basis to the NHSN. We stated that the current scoring methodology for the NHSN Dialysis Event reporting measure was finalized in the CY 2017 ESRD PPS final rule (81 FR 77881), and it was selected for two reasons. First, due to the seasonal variability of bloodstream infection rates, we stated that we wanted to incentive facilities to report the full 12 months of data and reward reporting consistency over the course of the entire performance period. Second, we stated that from the perspective of national prevention strategies and internal quality improvement initiatives, there was still value in collecting fewer than 12 months of data from facilities. For those reasons, we finalized a policy in the CY 2017 ESRD PPS final rule to award facilities 10 points for submitting 12 months of data, 2 points for reporting between 6 and 11 months of dialysis event data, and 0 points for reporting fewer than 6 months of data. See Table 7 for the scoring distribution finalized in the CY 2017 ESRD PPS final rule.

TABLE 7: Previously Finalized Scoring Distribution for the NHSN Dialysis Event Reporting Measure

Number of Reporting Months	Points Awarded to Facility
12 months	10 points
6-11 months	2 points
0-5 months	0 points

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38365) that as we have accumulated experience with this policy, we were concerned that new facilities and facilities for which CMS grants an ECE for part of the performance period that applies for a payment year were not eligible to receive a score on the NHSN Dialysis Event reporting measure because they were not eligible to report data for the full 12-month period. We stated that as a result, we did not believe that this policy appropriately accounted for the effort made by these facilities to report these data for the months in which they were eligible to report. For example, for PY 2020, the number of new facilities certified during the performance year (CY 2018) was 390 and the number of facilities granted an ECE during CY 2018 was 31, but none of those facilities was eligible to receive a score on the measure. We also stated our concern that if a facility was aware that it would not be eligible to receive a score on the NHSN Dialysis Event reporting measure, the facility would not be incentive to report data at all for that payment year.

We stated that as a result of these concerns, we reconsidered our policy. We proposed to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months. Beginning with the PY 2022 ESRD QIP, we also proposed to assess successful reporting based on the number of months facilities are eligible to report the measure. Under this proposal, facilities would receive credit for scoring purposes based on the number of months they successfully report data out of the number of eligible months. For example, if a facility had 10 eligible reporting months because it was granted an ECE for 2 months of the performance period, and reported data for those 10 eligible months, the facility would receive a score, whereas under the current policy, the facility would not receive a score. To accommodate this proposed change and to ensure that our scoring methodology appropriately incentive facilities to report data on the NHSN Dialysis Event reporting measure, even if they are not eligible to report data for all 12 months of a performance period, we also proposed to assign scores for reporting different quantities of data as summarized in Table 8.

TABLE 8: Proposed Scoring Distribution for the NHSN Dialysis Event Reporting Measure

Percentage of Eligible Months* Reported	Points Awarded to Facility
100% of eligible months	10 points
Less than 100% but no less than 50% of eligible months	2 points
Less than 50% of eligible months	0 points

*We define the term "eligible months" to mean the months in which dialysis facilities are required to report dialysis event data to NHSN per the measure eligibility criteria. This includes facilities that offer in-center hemodialysis and facilities that treat at least 11 eligible in-center hemodialysis patients during the performance period.

We stated our belief that it was important to encourage new facilities and facilities with an approved ECE to report complete and accurate dialysis event data to the NHSN for all the months in which they are eligible to submit data so that we would have as comprehensive as possible a view of these facilities' performance on this important clinical topic. We stated our belief that complete and accurate reporting of NHSN data was critical to maintaining the integrity of the NHSN surveillance system, enabled facilities to implement their own quality improvement initiatives, and enabled the Centers for Disease Control and Prevention (CDC) to design and disseminate prevention strategies. We stated our belief that the fairest way to balance these goals was to adopt a new NHSN Dialysis Event reporting measure policy focused more specifically on considering reporting successful based

on the number of months that a facility is eligible to report the measure. We did not propose changes to the NHSN BSI clinical measure's scoring methodology and stated that we will continue to require that facilities report data for the full 12 months of data in order to receive a score on that measure.

The comments and our responses to the comments on the proposed updates to the NHSN Dialysis Event reporting measure's scoring methodology are set forth below.

Comment: Some commenters expressed support for the proposed change to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months. One commenter also supported CMS's proposal to assess successful reporting based on the number of months facilities are eligible to report the measure, stating that it is important to encourage facilities to submit dialysis event data that is as complete and accurate as possible. Another commenter recognized the importance of having complete NHSN data and incentivizing all facilities to submit data regardless of the number of months they are eligible to report. This commenter further agreed that there is value in having new facilities and facilities with an approved ECE report data. One commenter suggested that we submit the measure to NQF for its review.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS not finalize the proposed scoring distribution for the NHSN Dialysis Event reporting measure and recommended that CMS amend the scoring distribution for the NSHN Dialysis Event reporting measure so that facilities earn 10 points for 100 percent of eligible months; 8 points for reporting 80 percent or more eligible months but less than 100 percent of eligible months; 4 points for reporting 50 percent or more eligible months but less than 80 percent of eligible months; and 0 points for reporting fewer than 50 percent of eligible months. Commenter stated that a facility that misses only 1 month of reporting will earn two points instead of the full ten points under the proposed scoring distribution and that such facilities should not be penalized so drastically. However, the commenter appreciates CMS' decision to allow facilities to receive credit on this measure based on the number of months they successfully report data out of the number of eligible months instead of penalizing new facilities unable to report for the full year and facilities with an approved ECE.

Response: We thank the commenter for its overall support of the proposal to allow new facilities and facilities with an approved ECE to receive credit for reporting data. We also thank the commenter for its suggested scoring distribution. However, we believe that the scoring methodology recommended by the commenter would allow facilities to be awarded too many points for reporting fewer than 100 percent of eligible months and could encourage facilities to pick and choose which months they want to report. We believe that our proposed methodology better incentivizes facilities to report data for all 12 months while also discouraging the selective suppression of data.

Final Rule Action: After considering public comments, we are finalizing the update to the scoring methodology for the NHSN Dialysis Event reporting measure as proposed.

b. Conversion of the Standardized Transfusion Ratio (STrR) Clinical Measure to a Reporting Measure

In the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197) we finalized the adoption of the Standardized Transfusion Ratio (STrR) clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP. We also finalized policies to score facility performance on the STrR clinical measure based on achievement and improvement in the PY 2018 ESRD QIP final rule (79 FR 66209). We finalized identical scoring policies for the STrR clinical measure in the PY 2019 ESRD QIP and the PY 2020 ESRD QIP in the CY 2016 ESRD PPS final rule (80 FR 69060 through 69061) and the CY 2017 ESRD PPS final rule (81 FR 77916), respectively.

After finalizing the STrR clinical measure in the CY 2015 ESRD PPS final rule, we submitted the measure to the NQF for consensus endorsement, but the Renal Standing Committee did not recommend it for endorsement, in part due to concerns that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the measure rates. Upon reviewing the committee's feedback, we revised the STrR clinical measure's specifications to address those concerns. The updated measure specifications for the STrR clinical measure contain a more restricted definition of transfusion events than was previously used in the STrR clinical measure. Specifically, the revised definition excludes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying International Statistical Classification of Diseases and Related Health Problems—9 (ICD–9) or ICD–10 procedure code or value code. As a result, the measure can identify transfusion events more specifically and with less bias related to regional coding variation, which means that the measure assesses a smaller number of events as well as a smaller range of total events.

Following this revision, we resubmitted the STrR clinical measure (NQF #2979) to NQF for consensus endorsement. The NQF endorsed the revised STrR clinical measure in 2016, and in the CY 2018 ESRD PPS final rule (82 FR 50771 through 50774), we finalized changes to the STrR clinical measure that aligned the measure specifications used for the ESRD QIP with the measure specifications that NQF endorsed in 2016 (NQF #2979), beginning with the PY 2021 ESRD QIP. We also finalized policies to score facility performance on the revised STrR clinical measure based on achievement and improvement (82 FR 50779 through 50780), and we subsequently finalized that those policies would continue for PY 2022 and in subsequent payment years (83 FR 57011).

Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the validity of the modified STrR measure (NQF #2979) finalized for adoption beginning with PY 2021. Commenters specifically stated that due to the new level of coding specificity required under the ICD–10–CM/PCS coding system, many hospitals are no longer accurately coding blood transfusions. The commenters further stated that because the STrR measure is calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals has negatively affected the validity of the STrR measure (83 FR 56993 through 56994).

In the CY 2020 ESRD PPS proposed rule (84 FR 38366), we stated that we are in the process of examining the concern raised by commenters about the validity of the modified STrR measure, and we stated that we had considered three alternatives for scoring the measure until we complete that process: (1) Assign the score that a facility would need to earn if it performed at the 50th percentile of national ESRD performance during the baseline year to every facility that would otherwise earn a score during the performance period below that median score, (2) align the measure specifications with those used for the measure prior to the PY 2021 ESRD QIP, and (3) convert the STrR clinical measure to a reporting measure.

We stated that we had considered the second alternative because the previously adopted measure

specifications for the STrR clinical measure include a more expansive definition of transfusions. However, we rejected the second policy alternative because that version of the STrR clinical measure was not endorsed by the NQF due to the concern expressed by the Renal Standing Committee that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the measure rates. We stated that we are in the process of evaluating the concern raised by commenters to the CY 2019 ESRD PPS proposed rule, and we stated our intention to present our analyses and measure changes to the NQF under an ad hoc review of the STrR clinical measure later in the year before making a final decision regarding implementation in the ESRD QIP. Additionally, we stated that any substantive changes to the STrR measure that result from this process might require a MAP review prior to any future implementation effort. We stated that under the first policy alternative, the Program would continue use of a measure endorsed by NQF, and if a facility did receive a payment reduction, it would not be due to its performance on the STrR clinical measure. Facilities would have to score below the median score used in the minimum TPS (mTPS) for a different measure in order to receive a payment reduction. If a facility scored at the median used in the mTPS calculation for all measures, it would receive the same TPS as the mTPS and therefore would not receive a payment reduction. However, we stated that we rejected the first policy alternative because it would score facilities based on their performance on a measure whose validity we are currently examining.

We stated that under the third policy alternative, we would be using a reporting measure that is based on an NQF-endorsed measure, but we would not be scoring facilities on the measure based on their performance. While the concerns regarding measure validity might call into question the capacity for current data to adequately capture transfusion rates attributable to facilities, we stated our belief that the transfusions captured by the measure are a conservative estimate of the number of events that actually occur, and that those events represent an undesirable health outcome for patients that is potentially modifiable by the dialysis facility through appropriate anemia management.

In light of the concerns raised about the validity of the STrR clinical measure, we stated that we are continuing to examine this issue. We stated our desire to ensure that the Program's scoring methodology results in fair and reliable STrR measure scores because those scores are linked to dialysis facilities' TPS and possible payment reductions. We stated our belief that the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that dialysis facilities are not adversely affected during our continued examination of the measure is to convert the STrR clinical measure to a reporting measure for the reasons discussed above.

We also proposed that, beginning with PY 2022, we would score the STrR reporting measure as follows: Facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. We proposed that in order to receive 10 points on the measure, a facility would need to report the data required to determine the number of eligible patient-years at risk and have at least 10 eligible patient-years at risk. We stated that a patient-year at risk was a period of 12-month increments during which a single patient is treated at a given facility. A patient-year at risk can be comprised of more than 1 patient if, when added together, their time in treatment equals a year. For example, if 1 patient is treated at the same facility for 4 months and a second patient is treated at a facility for 8 months, then the two patients would combine to form a full patient year.

We stated our belief that this scoring adjustment policy would enable us to retain an anemia management measure in the ESRD QIP measure set while we continue to examine the measure's validity concerns raised by stakeholders.

The comments and our responses to the comments on the proposal to convert the STrR measure from a clinical measure to a reporting measures are set forth below.

Comment: To ensure reporting accuracy of the STrR reporting measure, a commenter suggested that CMS apply an approach similar to that proposed for the NHSN Dialysis event measure. Commenter suggested that the STrR reporting measure should be based on the number of months a facility is eligible to report the measure.

Response: Unlike the NHSN Dialysis Event reporting measure, which is calculated using monthly data, the STrR reporting measure is calculated based on if a facility has at least 10 eligible patient-years at risk over a full year. Consequently, it is not feasible to calculate the STrR reporting measure using the number of months a facility is eligible to report the data.

Comment: Some commenters supported CMS's examination into the validity of the STrR measure and the proposal to convert it to a reporting measure. One commenter advised CMS to seek NQF review of the STrR clinical measure. Another commenter requested that CMS clarify and specify the STrR reporting requirements, including those pertaining to data elements, information submission, and the reporting schedule. One commenter suggested that the STrR clinical measure should only include patients who receive CKD anemia-related transfusions, given the number of acute and chronic conditions suffered by ESRD patients which may also necessitate a transfusion.

Response: We thank the commenter for its support of our proposal to convert the STrR clinical measure to a reporting measure. We agree with the commenter's recommendation to seek NQF review of the STrR clinical measure and have submitted the measure to NQF for review. Information gleaned from the review will be used to help support any future policies related to the STrR clinical measure. We acknowledge the commenter's recommendation to provide additional clarity regarding the scoring methodology for the STrR reporting measure and have provided additional details below. We note that the measure specifications for the STrR reporting measure remain the same as those finalized in the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197). However, because we are finalizing that we will now score the measure as a reporting measure, we will no longer score the measure based on the actual clinical values reported by facilities. Rather, for the STrR Reporting measure, facilities with at least 10 patient-years at risk will receive a score of 10; facilities with fewer than 10 patient-years at risk will not be eligible to receive a score on the STrR reporting measure. Specifically, the calculation of a patient-year at risk excludes the time periods when:

1. Patients are less than 18 years old.
2. Patients are on ESRD treatment for fewer than 90 days.
3. Patients are on dialysis at the facility for fewer than 60 days.
4. Time during which patients have a functioning kidney transplant (exclusion begins 3 days prior to the date of transplant).
5. Patients have not been treated by any facility for a year or longer.

6. Patients with a Medicare claim (Part A inpatient, home health, hospice, and skilled nursing facility claims; Part B outpatient and physician supplier) for one of the following conditions in the past year: Hemolytic and aplastic anemia, solid-organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, or sickle cell anemia.

7. Patient-months not within two months of a month in which a patient has $900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim.

8. Patients beginning 60 days after they recover renal function or withdraw from dialysis.

We also thank the commenter for its recommendation to include only patients who receive CKD anemia-related transfusions in the STrR clinical measure. We will assess the feasibility of this recommendation during our review of the STrR clinical measure.

Comment: Commenter expressed concern regarding the reliability and accuracy of the STrR clinical measure for small dialysis facilities, stating that it was often inappropriately scored. Commenter proposed removing the measure from the ESRD QIP until such issues are resolved.

Response: We thank the commenter for highlighting its concerns regarding the impact of the STrR clinical measure on small dialysis facilities. We will take this into account as we continue to examine the STrR clinical measure. In recognition of stakeholder concerns, we proposed to convert the STrR clinical measure to a reporting measure until all issues are resolved. We believe this approach allows us to continue assessing facilities on anemia management and avoid an adverse financial impact on facilities.

Comment: Commenter expressed concern regarding the validity of the STrR measure as a reporting measure, due to the accuracy difficulties presented by hospital coding practices. Commenter suggested that CMS adopt a risk-standardized rate measure as a potential alternative to submit for NQF endorsement.

Response: We disagree that variations in hospital coding practices would adversely impact facility performance on the STrR reporting measure. Based on the scoring methodology for the STrR reporting measure, facilities will receive 10 points on the measure if the facility successfully reports data on the measure and has at least 10 patient-years at risk during the performance period. We disagree with the commenter's suggestion to consider a risk-standardized rate instead of a ratio for the STrR clinical measure. Placing a facility's risk adjusted rate in context requires reference to a standard rate that applies to the population as a whole. The utilization of a ratio allows us to compare the ratio of the facility-adjusted rate to the standard rate. The ratio is also a scientifically valid approach and, in our experience, most people find the ratio to be understandable and to sufficiently convey the rates.

Comment: Several commenters recommended that CMS examine whether a hemoglobin threshold measure could be used as possible alternative to the STrR clinical measure in the ESRD QIP to satisfy its statutory anemia management measure requirement. Some commenters recommended replacing the STrR clinical measure with a measure of hemoglobin less than 10 g/dL. The commenters stated that a hemoglobin less than 10 g/dL measure is supported by considerable evidence, is most actionable for dialysis providers, and is operationally feasible. One commenter stated that hemoglobin is routinely measured, and its elevation is the most proximate effect of ESA administration. The commenter further stated that low hemoglobin is a predictor of transfusion risk, and that a hemoglobin of 10 g/dL is an effective level for reducing the need for transfusions. Commenter stated that CMS's removal of the hemoglobin measure from the ESRD QIP in 2012 was due to inconsistency with ESA labeling that was revised in June 2011 and that while the measure's standard became inappropriate, the measure is valid and places adequate anemia treatment under dialysis facility control.

Response: Use of a hemoglobin threshold measure has been previously considered and was not implemented based on several concerns. First, studies reporting results of anemia management in chronic dialysis settings typically result in hemoglobin distributions with relatively large outcome variation, creating concern that attempts at achievement of a specific target will result in a substantial minority of treated patients either well above or below the target at any point in time. Given the significant concerns about potential clinical risks of overtreatment with ESAs, implementation of a hemoglobin threshold could result in increased risk of ESA-related complication for the subset of patients above the threshold. One major consequence of under treatment is increased transfusion risk. Emphasis on minimizing avoidable transfusions in this population focuses on avoiding a major consequence of under-treatment without explicitly contributing to the risks associated with over-treatment with ESAs. This approach is consistent with the Food and Drug Administration (FDA) guidance for use of ESAs in this population. In addition, the available literature has not clearly established a minimum hemoglobin threshold that reliably maximizes the primary outcomes of survival, hospitalization, and quality of life for most patients. If new evidence becomes available, we will reassess the feasibility of replacing the STrR clinical measure with a hemoglobin measure as part of our future measure development work.

Comment: Commenter expressed concerns about the proposal to convert the STrR clinical measure to a reporting measure. Commenter agreed that facilities should not be adversely affected while CMS investigates the measure's validity concerns. However, the commenter expressed concerned about giving facilities credit for reporting a measure that is derived using hospital claims data and not values collected and reported in the facility. The commenter expressed concern that this approach stretches the ESRD QIP's statutory requirement to include a measure of anemia management to its limit. Commenter stated that CMS should examine anemia management practices in clinics through random audits or validation surveys to monitor compliance and identify signs of stinting.

Response: Anemia is a complication of end-stage renal disease that can be avoided if a patient's dialysis facility is undertaking proper anemia management. When anemia is not managed patients are subjected to unnecessary transfusions that increase morbidity and mortality. The STrR measure is calculated using data reported by hospitals because poor anemia management results in transfusions that most often occur in hospitals and not dialysis facilities. The commenter's recommendation to conduct random audits of anemia management practices is not feasible because we do not have the authority to examine anemia management practices in clinics through our validation activities. However, we will assess the feasibility of gathering more data about anemia management practices in clinics through our monitoring and evaluation work.

Comment: Commenter expressed concern that CMS may consider eliminating the STrR clinical measure

from the ESRD QIP. Commenter advocated preserving the STrR clinical measure in the ESRD QIP in PY 2022 and beyond, emphasizing the importance of a measure monitoring anemia management. Acknowledging accuracy issues associated with the current STrR clinical measure, commenter suggested that CMS determine an appropriate measure of anemia management to incentivize reducing the need for transfusions.

Response: We agree that it is important to include a measure monitoring anemia management in the program. However, in light of concerns regarding the STrR clinical measure, we do not believe it is appropriate to potentially penalize facilities for their performance on the clinical measure while we examine concerns raised by stakeholders. We believe that converting the STrR clinical measure to a reporting measure is appropriate to ensure that facilities are not penalized for their performance. If we conclude that the concerns about the STrR clinical measure raised by stakeholders are not supported by the evidence, we will consider reintroducing the measure or an updated version of the measure into the program through the rulemaking process.

Final Rule Action: After considering public comments, we are finalizing our proposals to convert the STrR clinical measure to a reporting measure and to update the scoring methodology as proposed.

c. MedRec Reporting Measure Scoring Methodology

In the CY 2019 ESRD PPS final rule (83 FR 57011), we finalized a policy to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP.

$$\left(\frac{\text{Number of patient-months successfully reporting data}}{\text{Number of eligible patient-months}} \text{ X } 12\right) - 2$$

We also stated that this equation was similar to the equation used for the Ultrafiltration reporting measure (81 FR 77917):

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \text{ X } 12\right) - 2$$

However, we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38367) that we inadvertently used the term ''patient-months'' in the MedRec reporting measure's scoring equation. We stated that we calculate a subset of our clinical measures using patient-months (the Kt/V Comprehensive clinical measure, the Standard Fistula Rate clinical measure, the Catheter Rate clinical measure, and the Hypercalcemia clinical measure) because patient-months is the unit of analysis based on their measure specifications. We stated that facility-months are generally used for a reporting measure because they assess the proportion of months in a year that a facility reported to CMS the data necessary to calculate the measure.

We stated that the use of facility-months for the MedRec reporting measure is also consistent with the scoring methodology we have used for all other reporting measures which require monthly reporting, including the Anemia Management reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP), the Serum Phosphorus reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP measure), and the Ultrafiltration reporting measure.

We therefore proposed to revise the scoring equation for the MedRec reporting measure so that the scoring methodology accurately describes our intended policy. We proposed to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP. We solicited public comments on this proposal.

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \text{ X } 12\right) - 2$$

Additionally, we stated that in section IV.B.4 of the CY 2019 ESRD PPS final rule, we had finalized a requirement for PY 2021 and beyond for facilities to begin collecting data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CMS Certification Number (CCN) becomes effective (83 FR 56999 through 57000). In section IV.C.4.c of the CY 2019 ESRD PPS final rule, we also finalized a policy for the MedRec reporting measure to begin scoring facilities with a CCN Open Date before the January 1st of the performance period (83 FR 57011). In section IV.C.6 of the CY 2019 ESRD PPS final rule (83 FR 57013 through 57014), we applied the updated reporting requirement for new facilities finalized in section IV.B.4 of the CY 2019 ESRD PPS final rule to the MedRec reporting measure eligibility requirements finalized in section IV.C.4.c of the CY 2019 ESRD PPS final rule. We specified in Table 23 of the CY 2019 ESRD PPS final rule that facilities with a CCN Open Date before October 1, 2019 would meet the

eligibility requirements for the MedRec reporting measure.

In order to ensure that there is no confusion regarding these requirements, we clarified in the CY 2020 ESRD PPS proposed rule (84 FR 38367) that for the MedRec reporting measure, facilities with a CCN Open Date before the October 1st prior to the performance period (which, for the PY 2022 ESRD QIP, would be a CCN Open Date before October 1, 2019) must begin collecting data on that measure.

The comments and our responses regarding the MedRec reporting measure's scoring methodology updates are set forth below.

Comment: Some commenters expressed concerns with our proposal to change the term ''patient-months'' in the MedRec reporting measure's scoring equation to the term ''facility months.'' Commenters stated that the term ''patient-months'' is more consistent with the NQF's definition, and disagreed with CMS's assertion that using ''facility months'' is more appropriate for a reporting measure. One commenter noted that this change could potentially result in lower scores for facilities that fail to perfectly report for all patients in all months. This commenter suggested that CMS use the ''patient-month'' metric used in the NQF-endorsed measure, or alternatively allow room for less than perfect reporting in the scoring equation.

Response: We acknowledge commenters' concerns and thank them for their feedback. While we reiterate our desire to align the scoring methodologies of all reporting measures, we also recognize the value of alignment with NQF measure specifications when possible and the incorporation of more outcomes focused measures in ESRD QIP. As such, we have been persuaded by commenters' concerns and given that the outcome of the MedRec measure is the provision of medication reconciliation services and their documentation by an eligible professional for patients attributed to dialysis facilities each month, we have decided to use ''patient-months'' instead of ''facility months'' when calculating ''eligible months'' for the MedRec measure. We believe this approach supports our desire to incorporate more outcomes-based measures in the ESRD QIP and is responsive to stakeholder concerns. We also plan to reevaluate other reporting measures for opportunities to more closely align them with NQF measure specifications.

Comment: One commenter supported the proposed change to the MedRec reporting measure scoring equation. Commenter agreed that MedRec is a reporting measure and should be scored like other reporting measures.

Response: We thank the commenter for its support of our proposal to score the MedRec measure consistent with how other reporting measures are scored. However, in recognition of stakeholder concerns regarding misalignment with the NQF endorsed measure specifications in addition to our desire to focus on more outcome-based measures, we plan to calculate the measure using patient months instead of facility months. This approach is aligned with our policy finalized in the CY 2019 ESRD PPS final rule (83 FR 57008 through 57010) and consistent with the NQF approved version of the measure.

Final Rule Action: After considering public comments, we are not finalizing the proposed update to the MedRec reporting measure's scoring methodology.

3. Update to the Eligibility Requirements for the PY 2022 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized a policy where, with respect to the NHSN Dialysis Event reporting measure, facilities are required to have a CCN Open Date on or before the October 1 prior to the performance period to be eligible to receive a score, beginning with the PY 2021 ESRD QIP (83 FR 56999 through 57000). In section IV.B.3.a of the CY 2020 ESRD PPS proposed rule, we proposed to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months and to assess successful reporting based on the number of months facilities were eligible to report the measure, beginning with the PY 2022 ESRD QIP. To accommodate this proposed policy, we proposed to remove the requirement that, to be eligible to receive a score on the NHSN Dialysis Event reporting measure, new facilities must have a CCN Open Date before October 1 prior to the performance period that applies to the payment year. We stated that Table 9 summarized the ESRD QIP's minimum eligibility requirements for scoring, including the proposed change to the eligibility requirement for the NHSN Dialysis Event reporting measure.

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TABLE 9: Proposed Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A as proposed	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)	10 patient-years at risk	N/A	N/A
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

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The comments and our responses regarding the minimum eligibility requirements are set forth below.

Comment: One commenter supported the removal of the CCN Open Date requirement for the Dialysis Event reporting measure. The commenter appreciated the interest in accurately capturing dialysis event data.

Response: We thank the commenter for its support of our proposal to remove the CCN Open Date requirement for the Dialysis Event reporting measure.

Comment: One commenter recommended that CMS give facilities a minimum of 90 days before being subject to the ESRD QIP's reporting requirements and exclude all facilities from ESRD QIP participation for the first 90 days after Medicare certification. Another commenter stated that new facilities have significant obligations when beginning operations and that they should not be penalized if they are unable to comply with CMS's reporting requirements.

Response: Under our current policy, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56669), new facilities are required to collect data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CCN becomes effective. We believe that this policy gives new facilities the flexibility they need to put into place the mechanisms needed in order to successfully participate in the ESRD QIP.

Final Rule Action: After considering public comments, we are finalizing as proposed the update to the NHSN Dialysis Event reporting measure's minimum eligibility requirements, which apply for the PY 2022 ESRD QIP and beyond.

4. Payment Reduction for the PY 2022 ESRD QIP

We stated in the CY 2020 ESRD PPS proposed rule that under our current policy, a facility will not receive a payment reduction in connection with its performance in the ESRD QIP for a payment year if it achieves a TPS that is at or above the minimum TPS that we establish for the payment year. We have defined the minimum TPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD

facility performance on all reporting measures.[40]

We also stated that our current policy, which is codified at § 413.177 of our regulations, is also to implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum TPS (76 FR 634 through 635).

For PY 2022, we estimated using available data that a facility must meet or exceed a minimum TPS of 53 in order to avoid a payment reduction. We noted that the mTPS estimated in the CY 2020 ESRD PPS proposed rule was based on data from CY 2017 instead of the PY 2022 baseline period (CY 2018) because CY 2018 data were not yet available.

We referred the reader to Table 4 for the estimated values of the 50th percentile of national performance for each clinical measure. We stated in the CY 2020 ESRD PPS proposed rule that under our current policy, a facility that achieves a TPS below 53 would receive a payment reduction based on the TPS ranges indicated in Table 10.

TABLE 10—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2022

Total performance score	Reduction (%)
100–53	0
52–43	0.5
42–33	1.0
32–23	1.5
22–0	2.0

We stated our intention to update the minimum TPS for PY 2022, as well as the payment reduction ranges for that payment year, in the CY 2020 ESRD PPS final rule.

The comments and our responses regarding the mTPS and payment reduction scale are set forth below.

Comment: One commenter stated that ESRD QIP penalties do not align with actual performance and are problematic in a program designed to only apply payment penalties. The commenter also expressed concern about the percentage of facilities anticipated to face penalties in PY 2020 and PY 2021 given that facility performance is improving overall.

Response: We thank the commenters for their feedback. However, we disagree that ESRD QIP penalties do not align with actual performance as our measure set assesses the degree to which evidence-based treatment guidelines are followed and assess the results of care. While we recognize the commenters concerns regarding the increase in payment penalties, our adoption of several outcome and patient experience of care measures (such as the STrR measure and the ICH CAHPS survey) with large variation in aggregate performance and room for improvement in more recent years of the QIP has contributed to an increase in the number of facilities that are receiving payment reductions. We also proposed domain weights changes to reflect the ESRD QIP's changing measure set. These changes have included alignment with our meaningful measures initiative and measure removal criteria (83 FR 56983 through 56989). We believe that some increases in payment penalties are inevitable as the Program's measure set changes, particularly as we accumulate sufficient data on reporting measures and convert them to more outcomes based measures or as actual performance data on new measures become available to establish real and not estimated performance standards. Because of these policy changes, we believe it is reasonable for the payment reductions to shift even if performance on some measures is comparatively high. Nevertheless, we will continue monitoring the amount of payment penalties imposed on facilities and facilities performance on our quality measures.

Comment: One commenter recommended that CMS share details about the methodology used to project payment adjustments. Commenter expressed concern regarding the lack of transparency in CMS's methodology for penalty projections. Commenter expressed concerns that the ESRD QIP has grown more complex over time and that relatively small changes to the Program can significantly change the distribution of payment penalties. Commenter stated that its analysis of the STrR proposal, for example, shows that the proposal resulted in a significant change in the number of facilities projected to receive a penalty in PY 2022. Commenter noted that CMS has implicitly acknowledged validity concerns based on its proposal to make data validation activities permanent.

Response: We describe the methodology used to project payment adjustments for the ESRD QIP in the Regulatory Impact Analysis section of both the ESRD PPS proposed and final rules each year. The most recent analyses, which apply to the PY 2022 and PY 2023 ESRD QIP, appeared in section XI.B.3.a of the CY 2020 ESRD QIP proposed rule and is in section X.B.3.b of this final rule. We calculate our projections by using the most recently available CROWNWeb and Medicare claims data. The list of eligible facilities is determined using the most recently published PPS eligible facility list. Simulated achievement scores are calculated using the achievement threshold and benchmark for each clinical measure. We use the achievement threshold and benchmark from the previous calendar year final rule rather than the standards published in the most current rule in order to simulate improvement in performance that we observe for some of the clinical measures from one year to the next. Improvement scores are calculated using the same methodology comparing the facility's performance year measure rate to the rate in the year prior. In the simulation, the performance year is based on the most recently available data, which will be at least 2 years prior to the actual performance year. Once the facility-level achievement and improvement scores are calculated, the measure weights are applied and the Total Performance Score is calculated. If a facility is missing one or more measures, then the measure weight(s) for the missing measures are redistributed to the other measures, based on the methodology proposed in the rule. For PY 2022 and PY 2023, the measure weights are redistributed equally among all other measures in the same domain. If we do not have data for a measure that is new to the ESRD QIP (for example, MedRec for PY 2022), we set the measure score to missing for all facilities and redistribute that weight equally among all other eligible measures in the same domain.

Finally, payment reductions are estimated using the mTPS that we calculate using the performance standards published in the previous year's final rule. Oftentimes the simulated mTPS is the same as the final mTPS proposed in the current rule, but we use an estimated simulated mTPS in order to simulate the differences in performance in prior years. Additionally, the methodology used to estimate performances scores is consistent with how the actual facility payment reductions are determined,

[40] We recently codified definitions for the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. When we codified the definition of the ''performance standard,'' we declined to include a reference to the 50th percent of national performance in that definition because the term ''performance standards'' applies more broadly to levels of achievement and improvement and is not a specific reference to the 50th percentile of national performance. Instead, we have incorporated the concept of the 50th percentile of national performance into the recently codified definition of the minimum TPS.

which use the mTPS, achievement threshold, and benchmark that are determined using data from the same year.

At the time the proposed rule was published, the most recently available data for a complete year was CY 2017. We have now updated the payment reductions that will apply to the PY 2022 ESRD QIP using CY 2018 data. The mTPS for PY 2022 will be 54, and the updated payment reduction scale is shown in Table 11.

TABLE 11—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2022 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–54	0
53–44	0.5
43–34	1.0
33–24	1.5
23–0	2.0

5. Data Validation for PY 2022 and Beyond

In the CY 2020 ESRD PPS proposed rule (84 FR 38368), we stated that one of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We stated that the ESRD QIP includes two validation studies for this purpose: The CROWNWeb data validation study (OMB Control Number 0938–1289) and the NHSN validation study (OMB Control Number 0938–1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb data validation study as a permanent feature of the Program (83 FR 57003). We stated that under that policy, we will continue validating CROWNWeb data in PY 2022 and subsequent payment years, and we will deduct 10 points from a facility's TPS if it is selected for validation but does not submit the requested records.

We also adopted a methodology for the PY 2022 NHSN validation study, which targets facilities for NHSN validation by identifying facilities that are at risk for under-reporting. A sample of 300 facilities will be selected, and each facility will be required to submit 20 patient records covering 2 quarters of data reported in the performance year (for PY 2022, this would be CY 2020). For additional information on this methodology, we referred readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

In the CY 2020 ESRD PPS proposed rule, we proposed to continue using this methodology for the NHSN validation study for PY 2023 and subsequent years because based on a recent statistical analysis conducted by the CDC, we have concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities. We stated that this sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on those results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP are accurate, we proposed to continue use of this methodology in the PY 2023 NHSN validation study and for subsequent years.

Additionally, as we finalized for CROWNWeb validation, we proposed to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and proposed to continue for PY 2023 and subsequent years. We stated our belief that the purpose of our validation programs is to ensure the accuracy and completeness of data that are scored under the ESRD QIP and that validating NHSN data using this methodology achieves that goal. Now that we have adopted a larger sample size of 300 facilities for the NHSN validation study and have thus ensured enough precision within the study, we believe that making the validation study permanent will show our commitment to accurate reporting of the important clinical topics covered by the NHSN measures that we have adopted. We welcomed public comments on these proposals.

The comments and our responses to the comments on our data validation proposals are set forth below.

Comment: Some commenters supported continued use of the CROWNWeb validation study and the 10-point non-compliance penalty. One commenter also supported the permanent adoption of the NHSN validation methodology and the continued use of the PY 2022 methodology in future payment years.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS adopt an alternative data validation approach, such as requesting data that only applies to the specific area of the validation, giving facilities more time to comply with data requests, and using electronic data exchange. The commenter expressed concerns about the burden placed on facilities to conduct data validation activities. The commenter also stated that CMS is not considering facility burden for validation activities.

Response: We will consider these recommendations during future rulemaking. Our validation studies are conducted within a timeframe that is consistent with our operational schedule. Currently facilities are given 60 days to respond to data request. We do not believe that increasing the time is feasible because our goal is to provide facilities with timely feedback about reporting accuracy. We disagree with the characterization that CMS is not taking facility burden into consideration for these validation activities. Each year we calculate facility burden associated with our validation activities and submit this information as part of our Paperwork Reduction Act (PRA) submission package. For example, in our most recent PRA package, we estimated that the burden associated with the collection of information for our PY 2022 NHSN validation activities is 10 hours annually and $423 per facility, which we believe is a minimal burden on facilities. Additionally, given that our validation activities are widely supported by stakeholders and encourage improvements in data completeness and accuracy, we believe the value of our validation activities outweigh the current estimated burden posed on facilities. Currently, our validation activities are restricted to measures that utilize CrownWeb or NHSN as their primary data sources. If we impose further restrictions on data collected for validation actions, our ability to measure the accuracy of data submitted to CROWNWeb or NHSN will be severely limited. We also encourage facilities to submit data electronically through our secured transfer file system instead of submitting hard copies of requested records. We believe this approach is more efficient and effective for facilities.

Final Rule Action: After consideration of public comments we received, we are finalizing as proposed the continuation of the PY 2022 NHSN validation study methodology in PY 2023 and subsequent years as well as adoption of the NHSN validation study as a permanent feature of the Program.

E. Requirements for the PY 2023 ESRD QIP

1. Continuing Measures for the PY 2023 ESRD QIP

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that, under our previously adopted policy, we were continuing all measures from the PY 2022 ESRD QIP for PY 2023. We did not propose to adopt any new measures beginning with the PY 2023 ESRD QIP.

2. Proposed Performance Period for the PY 2023 ESRD QIP and Subsequent Years

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated our continued belief that 12-month performance and baseline periods would provide us sufficiently reliable quality measure data for the ESRD QIP. We therefore proposed to establish CY 2021 as the performance period for the PY 2023 ESRD QIP for all measures. Additionally, we proposed to establish CY 2019 as the baseline period for the PY 2023 ESRD QIP for all measures for purposes of calculating the achievement threshold, benchmark, and minimum TPS, and CY 2020 as the baseline period for the PY 2023 ESRD QIP for purposes of calculating the improvement threshold. Beginning with PY 2024, we proposed to adopt automatically a performance and baseline period for each year that is 1-year advanced from those specified for the previous payment year. For example, under this policy, we would automatically adopt CY 2022 as the performance period for the PY 2024 ESRD QIP. We would also automatically adopt CY 2020 as the baseline period for purposes of calculating the achievement threshold, benchmark, and minimum TPS and CY 2021 as the baseline period for purposes of calculating the improvement threshold, for the PY 2024 ESRD QIP. We welcomed public comments on these proposals.

The comments and our responses to the comments on our proposals for establishing the performance and baseline periods are set forth below.

Comment: One commenter expressed support for CMS's proposal to codify the automatic adoption of a baseline period and a performance period for each payment year that is 1-year advanced from those specified for the previous payment year. The commenter also expressed its appreciation for the predictability and efficiency provided by this proposal.

Response: We thank the commenter for its support.

Final Action Decision: After considering public comments received, we are finalizing our proposals for establishing the performance and baseline periods as proposed.

3. Performance Standards for the PY 2023 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we referred readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We stated that we recently codified definitions for the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2023 ESRD QIP

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that at that time, we did not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we did not have CY 2019 data. We stated our intention to publish these numerical values, using CY 2019 data, in the CY 2021 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2023 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that we would continue use of those performance standards in PY 2023.

4. Scoring the PY 2023 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(d).[41]

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that we were not proposing to change these scoring policies.

b. Scoring Facility Performance on Reporting Measures

In the CY 2019 ESRD PPS final rule, we codified our policy for scoring performance on reporting measures at § 413.178(d),[42] and we finalized the continued use of existing policies for scoring performance on the Ultrafiltration Rate reporting measure and the MedRec reporting measure (83 FR 57011). In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that we would continue use of the Ultrafiltration Rate reporting measure's scoring policy in PY 2023. In section IV.B.3.c of the CY 2020 ESRD PPS proposed rule, we proposed to use facility-months instead of patient-months when scoring the MedRec reporting measure and clarified our intention to begin scoring new facilities with a CCN Open Date before the October 1st of the year prior to the performance period rather than before the January 1st of the performance period. We stated in the CY 2020 ESRD PPS proposed rule that those proposals, if finalized, would apply to PY 2023 and subsequent payment years. In Section IV.D.2.c of this final rule, we did not finalize our proposal to update the scoring methodology for the MedRec reporting measure, so that measure will be scored in accordance with the methodology we finalized in the CY 2019 ESRD PPS final rule. (83 FR 57008 through 57010).

5. Weighting the Measure Domains and the TPS for PY 2023

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that under our current policy, we have assigned the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS, for the PY 2022 ESRD QIP (83 FR 57011 through 57012).

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures in the PY 2022 ESRD QIP (83 FR 57011 through 57012). In the CY 2020 ESRD PPS proposed rule (84 FR 38370), we proposed to continue use of

[41] Please note that we are finalizing our proposal to redesignate § 413.178(d) as § 413.178(e) in this final rule.

[42] Please note that we are finalizing our proposal to redesignate § 413.178(d) as § 413.178(e) in this final rule.

the PY 2022 measure weights for the PY 2023 ESRD QIP and subsequent payment years. We also proposed to continue use of the PY 2022 measure weight redistribution policy in the PY 2023 ESRD QIP and subsequent payment years. We solicited public comments on these proposals.

We also noted that under our current policy, a facility must be eligible to be scored on at least one measure in two of the four measures domains in order to be eligible to receive a TPS (83 FR 57012).

The comments and our responses to the comments on our measure weight assignments and weight redistribution proposals are set forth below.

Comment: One commenter expressed concern with the weight of the MedRec reporting measure within the Safety Measure Domain, and its application to home dialysis facilities. The commenter noted that because other measures within the domain do not apply to home dialysis facilities, the MedRec reporting measure effectively has more weight in the ESRD QIP TPS than otherwise intended. To remedy this concern, commenter suggested that CMS move the MedRec reporting measure from the Safety Measure Domain to the Care Coordination Measure Domain. The commenter also suggested that CMS add the following patient-level exclusions for home dialysis facilities: (1) Patients not assigned to the facility for the entire reporting month, and (2) patient-months where there is a more than one treatment modality.

Response: In the CY 2019 ESRD PPS final rule (83 FR 57003 through 57010), we finalized the MedRec reporting measure for the ESRD QIP measure set, beginning with PY 2022. The MedRec reporting measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the dialysis patient population because those patients typically take a large number of medications. Inclusion of the MedRec measure in the ESRD QIP measure set aligns with the Meaningful Measure Initiative priority area of making care safer by reducing harm caused by care delivery. As noted in the CY 2019 ESRD PPS final rule, while we agree that medication reconciliation can be considered a measure of care coordination, we believe that it is more properly aligned with patient safety because patients can be harmed by medication errors. While it is possible that MedRec will be weighted more for home dialysis facilities, we do not believe this is inappropriate because regardless of the facility type, all facilities are required to provide high quality services to patients that do not cause harm. Additionally, in accordance with our monitoring and evaluation efforts, we plan to monitor the impact of measures on dialysis facilities and the quality of care provided to facilities and propose any changes we think are warranted. We thank the commenter for its recommendation regarding patient-level exclusions to the measure; however these comments are out of scope given that we are not proposing to make any updates to the underlying measure specifications. Nevertheless, we will review and assess the feasibility of the commenter's recommendation and if warranted, consider in future rulemaking.

Comment: One commenter expressed concern that the current weighting of measure domains, given the increasing number of quality measures, may dilute the importance of each individual measure and potentially result in decreased quality of care. The commenter recommended that we continually reevaluate the ESRD QIP to ensure that the measures included are all meaningful. Another commenter stated that the weighting assigned to the SRR and SHR measures (12 percent each) is too high given the amount of control that dialysis facilities have over admissions and readmissions to the hospital. The commenter stated that we should reduce the weights assigned to those measures and increase the weighting applied to measures in the Clinical Care and Safety domains.

Response: We disagree that our current measure domains and weighting dilutes the importance of each individual measure and decreases quality of care. We believe our core set of measures addresses areas that are agency priorities, safeguard public health, and are meaningful to patients. Further, we take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, patient and provider burden) the number of measures and measure topics in the domain, how much experience facilities have had with the measures and measure topics in the domain, and how well the measures align with CMS's highest priorities for quality improvement from patients receiving dialysis. We also continuously review our existing measures and weights and propose changes that we think are warranted. We disagree with the commenter's recommendation to reduce the weight of SHR and SRR. We believe that our weights for SRR and SHR are appropriate given that reducing hospitalizations and readmission is a top policy goal for CMS. We also continue to believe that the SHR and SRR measures, along with other measures in the ESRD QIP, ensure that dialysis facilities fulfill their shared responsibilities to coordinate with other types of providers to provide the best possible care and ensure their patients' continued health.

Comment: Commenter requested clarification on how the TPS would be reweighted for facilities that are unable to reach the required 30 ICH–CAHPS survey count. Commenter suggested that many facilities will not receive ICH–CAHPS scores and noted that the additional clarity would be helpful to those facilities.

Response: In the CY 2019 ESRD PPS final rule (83 FR 56998), we finalized a policy that would redistribute the weights of any measures for which the facility does not receive a score to the remaining measures proportionately based on their measure weight as a percent of the TPS. This redistribution would occur across all measures regardless of their domain. If a facility did not receive an ICH CAHPS score, one-third of the Patient & Family Engagement Domain's weight of 15 percent would be distributed to each of the three remaining domains and evenly split among measures within each domain. We believe this approach addresses concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures.

Final Rule Action: After considering the public comments we received, we are finalizing as proposed continuation of the PY 2022 measure weights in PY 2023 and subsequent payment years as well as our continued use of the PY 2022 weight redistribution policy in PY 2023 and subsequent payment years.

V. Establishing Payment Amounts for New Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items and Services (Gap-Filling)

A. Background

1. Calculating Fee Schedule Amounts for DMEPOS Items and Services

Section 1834(a) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for DME other than customized items defined at 42 CFR 414.224 and items included in a competitive bidding program and furnished in a competitive bidding area under section 1847(a) of the Act. Section 1834(h) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for most prosthetic

devices, orthotics, and prosthetics other than off-the-shelf orthotics included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act. Section 1834(i) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for surgical dressings. Section 1833(o)(2)(A) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount in accordance with section 1834(h) of the Act for custom molded shoes, extra-depth shoes, and inserts. Section 1842(s) of the Act authorizes payment based on the lesser of the supplier's actual charge or a fee schedule amount for parenteral and enteral nutrients, equipment, and supplies (PEN), other than enteral nutrients, equipment, and supplies included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act, and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office. The fee schedule amounts established for these items and services are based on payments made previously under the reasonable charge payment methodology, which is set forth in section 1842(b) of the Act and in our regulations at 42 CFR 405.502. Generally, reasonable charge determinations are based on customary and prevailing charges derived from historic charge data. The fee schedule amounts for DME, prosthetic devices, orthotics, prosthetics, and custom molded shoes, extra-depth shoes, and inserts are based on average reasonable charges from 1986 and 1987. The fee schedule amounts for surgical dressings are based on average reasonable charges from 1992. The fee schedule amounts for PEN are calculated on a nationwide basis and are the lesser of the reasonable charges for 1995, or the reasonable charges that would have been used in determining payment for these items in 2002 under the former reasonable charge payment methodology (§ 414.104(b)). The fee schedule amounts for splints and casts are based on reasonable charges for 2013 and the fee schedule amounts for intraocular lenses inserted in a physician's office are based on reasonable charges for 2012. Pursuant to sections 1834(a)(14)(L), 1834(h)(4)(xi), and 1842(s)(1)(B)(ii) of the Act, the DMEPOS fee schedule amounts are generally adjusted annually by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding year reduced by a productivity adjustment. The Medicare payment amount for a DMEPOS item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Medicare Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met.

The statute does not specify how to calculate fee schedule amounts when the base reasonable charge data does not exist. As discussed later on, since 1989, we have used a process referred to as ''gap-filling'' to fill the gap in the reasonable charge data for new DMEPOS items, which are newly covered items or technology. The gap-filling process is used to estimate what Medicare would have paid for the item under the reasonable charge payment methodology during the period of time from which reasonable charge data is used to calculate the fee schedule amounts, or the fee schedule ''base period'' (for example, 1986 and 1987 for DME). Various methods have been used by CMS and its contractors to gap-fill DMEPOS fee schedule amounts including use of fees for comparable items, supplier prices, manufacturer's suggested retail prices (MSRPs), wholesale prices plus a markup percentage to convert the prices to retail prices, or other methods. In any case where prices are used for gap-filling, the prices are deflated to the fee schedule base period by the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the price is in effect to the mid-point of the fee schedule base period. Program guidance containing instructions for contractors (mainly for use by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for gap-filling DMEPOS fee schedule amounts is found at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100–04). The instructions indicate that the DMEPOS fee schedule for items for which reasonable charge data were unavailable during the fee schedule base period are to be gap-filled using the fee schedule amounts for comparable items or supplier price lists with prices in effect during the fee schedule base period. The instructions specify that supplier price lists include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data (for example, fee schedule amounts comprised of the median of the commercial pricing information adjusted as described below). Mail order catalogs are suitable sources of routinely available price information for items such as urological and ostomy supplies which require frequent replacement. We issued Transmittal 4130, Change Request 10924 dated September 14, 2018 which updated the manual instruction to clarify that supplier price lists can include internet retail prices or verifiable information from supplier invoices and non-Medicare payer data. Prior to 2018, non-Medicare payer data had not been included to establish gap-filled DMEPOS fee schedule amounts. CMS and its contractors have used internet retail prices in the past in addition to catalog prices, as well as wholesale prices plus a retail price mark up, and on one occasion hospital invoices plus a 10 percent markup as a source for commercial pricing information.

In 2015, when revising the DME MAC statement of work, CMS clarified to the DME MACs that MSRP should not be used for gap-filling due to CMS's concerns that MSRPs may not represent routinely available supplier price lists, which are incorporated for supplier charges in calculating fee schedule amounts that the statute mandates be based on historic reasonable charges. Although MSRPs were used in certain cases in the past to gap-fill DMEPOS fee schedule amounts, our experience has revealed the retail prices suggested by manufacturers often are inflated and do not reflect commercial competitive pricing, or a price that is paid to a supplier for furnishing items and services. Using MSRPs to gap-fill DMEPOS fee schedule amounts led to excessive fee schedule amounts compared to fees established for other DMEPOS items paid for in 1986, 1987, 1992, 2001, or other fee schedule base periods. In some cases, a single manufacturer may produce a new item, and pricing information may therefore be limited to the MSRP. In these cases, unlike other items and services paid for under Medicare, there is not yet independently substantiated pricing information. In addition, similar items may not be available to create competition and to potentially limit the price a sole source manufacturer charges for the new item. We believe the MSRP may represent the amount the manufacturer charges to Medicare and other health insurance payers before pricing is established in a competitive market by suppliers furnishing the product and competitor products.

Currently, when we release our program instruction announcing

updates to the DMEPOS fee schedule, we include a list of new Healthcare Common Procedure Coding System (HCPCS) codes, which are added to the DMEPOS fee schedule. Also, we release updated DMEPOS fee schedule amounts in fee schedule files to our contractors and available online at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html*.

If a HCPCS code for a new item is added and takes effect, and the fee schedule amounts for the new code have not yet been added to the DMEPOS fee schedule file, our contractors establish payment on an interim basis using local fee schedule amounts gap-filled in accordance with the program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual until the fee schedule amounts on the national files are available.

2. Coding for New DMEPOS Items

The HCPCS is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs. Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes identifying primarily medical services and procedures furnished by physicians and other health care practitioners, published and maintained by the American Medical Association. Level II of the HCPCS codes primarily identifies items, supplies, services and certain drugs used outside the practitioner setting. Assignment of a HCPCS code is not a coverage determination and does not imply that any payer will cover the items in the code category.

In 2001, section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) mandated the establishment of procedures for coding and payment determinations for new DMEPOS items under Medicare Part B that permit public consultation in a manner consistent with the procedures established for implementing ICD–9–CM coding modifications. As a result, beginning in 2002, after the HCPCS Workgroup has developed its preliminary decision, these preliminary decisions are made available to the public via our website and public meetings are scheduled to receive public comment on the preliminary decisions.

Following the HCPCS public meetings, we make a final decision on each new DMEPOS code request and payment category. Then, we prepare and release the HCPCS and DMEPOS fee schedule files and program instructions for the next update (annual or quarterly) to our contractors and via our website for public access. Also, a summary of the final coding and payment category decisions is made available on our website. See the following websites for more information:

- HCPCS Files: *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html*;
- DMEPOS Fee Schedule Files: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html*;
- Program Instructions: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html*; and
- Public Meeting Summaries: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html*.

Typically, more than 100 applications are submitted to the CMS HCPCS Workgroup each year, with approximately one-third requesting new or revised DMEPOS codes. The list of approved new DMEPOS codes is not finalized until shortly before the release of the updated HCPCS file, which in some cases, leaves very short timeframes to prepare and release the updated DMEPOS fee schedule.

3. Continuity of Pricing

Instructions for contractors addressing how to establish DMEPOS payment amounts following updates to HCPCS codes are contained at section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. When an item receives a new HCPCS code, it does not necessarily mean that Medicare payment on a fee schedule basis has never been made for the item described by the new code. If a new code is established, CMS and our contractors follow the instructions in section 60.3.1 to make every effort to determine whether the item has a pricing history. If there is a pricing history, that is, the item(s) and services described by the new code were paid for in the past under existing codes based on the fee schedule amounts for these codes, the fee schedule amounts previously used to pay for the item are mapped or cross walked to the new code(s) for the item to ensure continuity of pricing. Since there are different kinds of coding changes, there are various ways pricing is cross walked from old codes to new codes, which are addressed in our program instructions at section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. For example, when the code for an item is divided into multiple codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. However, when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts for the single code are applied to each of the new codes. Conversely, when the codes for the components of an item are combined in a single global code, the fee schedule amount for the new code is established by totaling the fee schedule amounts used for the components (that is, the total of the fee schedule amounts for the components is used to determine the fee schedule amount for the global code). However, when the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes. These instructions are used to ensure continuity of pricing under the Medicare program, but do not apply to items when a pricing history does not exist, that is, in situations where an item was not paid for under a HCPCS code or codes with an established DMEPOS fee schedule amount(s). The gap-filling process only applies to items not assigned to existing HCPCS codes with established fee schedule amounts and items that were not previously paid for by Medicare under either a deleted or revised HCPCS code.

4. Authority for Establishing Special Payment Limits

Section 1842(b)(8) of the Act authorizes CMS to adjust payment amounts if, subject to the factors described in the statute and the regulations, CMS determines that such payment amounts are grossly excessive or grossly deficient, and therefore are not inherently reasonable. CMS may make a determination that would result in an increase or decrease of more than 15 percent of the payment amount for a year only if it follows all of the requirements under paragraphs (B), (C), and (D) of section 1842(b)(8) of the Act. Under these requirements, CMS must take certain factors into account, such as whether the payment amount does not reflect changing technology. In addition, section 1842(b)(9) of the Act mandates a specific process that CMS must follow when using this ''inherent reasonableness'' authority (IR authority) to adjust payment amounts by more

than 15 percent a year. CMS has established the methodology and process for using the IR authority at §§ 405.502(g) and (h). Use of the IR authority involves many steps mandated under sections 1842(b)(8) and (9) of the Act, which can include consulting with supplier representatives before making a determination that a payment amount is not inherently reasonable; publishing a notice of a proposed determination in the **Federal Register** which explains the factors and data taken into account; a 60-day comment period; and publishing a final notice, again explaining the factors and data taken into account in making the determination. Medicare can only make payment adjustments for ''inherent reasonableness'' that would result in a change of more than 15 percent per year by going through the process outlined in the statute and at §§ 405.502(g) and (h). As a result, the requirements under sections 1842(b)(8) and (9) of the Act regarding ''inherent reasonableness'' adjustments are applicable to special payment limits established in cases where supplier or commercial prices used for gap-filling decrease by more than 15 percent.

Examples of factors that may result in grossly excessive or grossly deficient payment amounts are set forth at § 405.502(g)(1)(vii) and include, but are not limited to, the following:

- The market place is not competitive.
- Medicare and Medicaid are the sole or primary sources of payment for a category of items and services.
- The payment amounts for a category of items and services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.
- The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services.
- Payment amounts for a category of items and services are grossly higher or lower than acquisition or production costs for the category of items and services.
- There have been increases in payment amounts for an item or service that cannot be explained by inflation or technology.
- Payment amounts for a category of items or services are grossly higher or lower than payments made for the same category of items or services by other purchasers in the same locality.
- A new technology exists which is not reflected in the existing payment allowances.

Prior to making a determination pursuant to section 1842(b)(8) of the Act that would result in an increase or decrease of more than 15 percent in a payment amount for a year, CMS is required to consult with representatives of suppliers or other individuals who furnish an item or service. In addition, section 1842(b)(8)(D) of the Act mandates that CMS consider the potential impact of a determination pursuant to section 1842(b)(8) that would result in a payment amount increase or decrease of more than 15 percent for a year on quality, access, beneficiary liability, assignment rates, and participation of suppliers. In establishing a payment limit for a category of items or services, we consider the available information relevant to the category of items or services in order to establish a payment amount that is realistic and equitable. Under § 405.502(g)(2), the factors we may consider in establishing a payment limit include the following:

- Price markup. The relationship between the retail and wholesale prices or manufacturer's costs of a category of items and services. If information on a particular category of items and services is not available, we may consider the price markup on a similar category of items and services and information on general industry pricing trends.
- Differences in charges. The differences in charges for a category of items and services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.
- Costs. Resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items and services.
- Use. Imputing a reasonable rate of use for a category of items or services and considering unit costs based on efficient use.
- Payment amounts in other localities. Payment amounts for a category of items and services furnished in another locality.

In determining whether a payment amount is grossly excessive or grossly deficient, and in establishing an appropriate payment amount, we use valid and reliable data. To ensure the use of valid and reliable data, we must meet the criteria set forth at § 405.502(g)(4), to the extent applicable. This includes, but is not limited to, considering the cost of the services necessary to furnish a product to beneficiaries if wholesale costs are used.

If we make a determination that a special payment limit is warranted to adjust a grossly excessive or grossly deficient payment amount for a category of items and services by more than 15 percent within a year, we must publish in the **Federal Register** a proposed and final notice of any special payment limits before we adopt the limits, with at least a 60-day period for public comments on the proposed notice. The proposed notice must explain the factors and data considered in determining the payment amount is grossly excessive or deficient and the factors and data considered in determining the special payment limits. The final notice must explain the factors and data considered and respond to public comment.

5. The 2006 Proposed Rule and 2018 Solicitation of Comments on Gap-Filling

On May 1, 2006, we published several proposed changes for the gap-filling process in our rule titled ''Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'' (71 FR 25687 through 25689). The May 2006 proposed rule discussed the existing gap-filling process and the results of pilot assessments conducted by two CMS contractors to assess the benefits, effectiveness, and costs of several products. The purpose of the pilot assessments was to compile the technical information necessary to evaluate the technologies of the studied products with the objective of making payment and HCPCS coding decisions for new items. The contractors evaluated the products based on: (1) A functional assessment; (2) a price comparison analysis; and (3) a medical benefit assessment. The functional assessment involved evaluating a device's operations, safety, and user documentation relative to the Medicare population. The price comparison analysis involved determining how the cost of the product compared with similar products on the market or alternative treatment modalities. The medical benefit assessment focused on the effectiveness of the product in doing what it claims to do.

As a result of the pilot studies, we proposed to use what we referred to as the ''functional technology assessment'' process, in part or in whole, to establish payment amounts for new items (71 FR 25688). We also suggested that we would make every effort to use existing fee schedule amounts or historic Medicare payment amounts for new HCPCS codes; that we would retain the method of using payment amounts for comparable items (properly calculated fee schedule amounts, or supplier price lists); but that we would discontinue the

practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period. In response to our proposal, many commenters recommended a delay for finalizing regulations for the gap-filling process due to an overwhelming number of new proposals in the rule, including the DMEPOS competitive bidding program. In our final rule published on April 10, 2007 in the **Federal Register** titled ''Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,'' we did not finalize our proposals for regulations for the gap-filling process, as a result of commenters feedback. We stated that we would address comments and regulations for the gap-filling process in future rulemaking (72 FR 17994).

In our CY 2019 ESRD PPS proposed rule titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS'', we issued a request for information on the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. We solicited comments for information on how the gap-filling process could be revised in terms of what data sources or methods could be used to estimate historic allowed charges for new items' technologies in a way that satisfies the payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services. In the final rule, we summarized the comments received and stated we would consider these comments carefully as we contemplate future policies (83 FR 57046 through 57047). The majority of the comments focused on the aspects of transparency, sources of information, and comparable items in the gap filling process. Overall, the commenters recommended that CMS increase transparency for stakeholders during the gap-filling process for establishing fees for new DMEPOS items and revise the process for filling the gap in the data due to the lack of historic reasonable charge payments by estimating what the historic reasonable charge payments would have been for the items from a base year of 1986 and 1987 and inflating to the current year. Also, some commenters did not want CMS to include internet or catalog pricing in the gap-filling process unless there is evidence that the price meets all Medicare criterion and includes all Medicare required services. The commenters stated that internet and catalog prices do not reflect the costs to suppliers of compliance with the many Medicare requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation, and thereby do not contribute to a reasonable payment level. Furthermore, commenters suggested developing additional guidelines and definitions for determining whether a Medicare covered DMEPOS item is comparable to a new item for the purpose of assigning a fee schedule amount to a new item. The commenters elaborated that in order for an item to be comparable to another item, both should have similar features and function, should be intended for the same patient population, for the same clinical indicators, and to fill the same medical need. In addition, some commenters endorsed the addition of a weighting calculation to apply to a median price that would factor in the existing market demand/share/utilization of each product and price included in the array of retail prices used for gap-filling using supplier price lists. Also, the commenters expressed concern that the current gap-filling methodology does not always incorporate comparability analysis and assumes that all products within a given HCPCS code have equal characteristics, minimum specifications, and the gap-filling method does not account for relative quality, durability, clinical preference, and overall market demand.

B. Current Issues

In the CY 2020 DMEPOS proposed rule (84 FR 38373–38375), we discussed that concerns have been raised by manufacturers and stakeholders about CMS' processes for establishing fees for new DMEPOS items. In particular, our process for reviewing information and data when establishing fee schedule amounts for new DMEPOS items in some instances has led to confusion among some stakeholders. For example, some manufacturers have been confused in the past about why fee schedule amounts for comparable items are sometimes used to establish fee schedule amounts for new items and how CMS determines that new items are comparable to other DMEPOS items. Some have asked for a process that is more predictable in determining the sources of data CMS would use to establish fee schedule amounts for new DMEPOS items and services, given the amount of time and money associated with investing in the development of new technology for DMEPOS items and services.

Major stakeholder concerns related to gap-filling DMEPOS fee schedule amounts have been: (1) How CMS determines that items and services are comparable; (2) sources of pricing data other than fees for comparable items; (3) timing of fee schedule calculations and use of interim fees; (4) public consultation; (5) pricing data and information integrity; and (6) adjustment of newly established fees over time.

1. Code or Item Comparability Determinations

A major stakeholder concern that we have heard frequently from manufacturers is that they do not agree that their newly developed DMEPOS item is comparable to older technology DMEPOS items and services (84 FR 38374). Our program instructions set forth a process to establish DMEPOS payment amounts following updates to HCPCS codes in section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. Under this process, using fee schedule amounts for comparable items to establish fee schedule amounts for new items can involve a number of pricing combinations including, but not limited to: (1) A one to one mapping where the fees for one code are used to establish the fees for a new code, (2) the use of fees for a combination of codes with established fee schedule amounts; (3) the use of fees for one or more codes minus the fees for one or more other codes identifying a missing feature(s) the newer item does not include; or (4) the use of one or more codes plus additional amounts for the costs of an additional feature(s) the newer items has that the older item(s) does not include. The benefit of using fee schedule amounts for comparable items, especially items that CMS paid for during the fee schedule base period, is that average reasonable charge data or pricing data that is closer to the fee schedule base period is used in establishing the fee schedule amounts, and this better reflects the requirements of the statute than using more recent supplier prices as a proxy for reasonable charge data from the past. In addition, establishing fees for a new item that are significantly higher than fees for

comparable items based on reasonable charge data can result in a competitive advantage for the new item because the suppliers of the older item are paid considerably less than the suppliers of the new item even though the new item is comparable to the older item. This could create an incentive for suppliers to furnish the new item more often than the older item, which would create an unfair advantage for the manufacturer(s) of the new item.

As explained in the CY 2020 DMEPOS proposed rule (84 FR 38374), in an effort to consider the concerns about our process for establishing payment amounts for new DMEPOS item and services, we undertook a review of the major components and attributes of DMEPOS items that we evaluate when determining whether items are comparable in order to develop and propose a standard for when and how fees for comparable items would be used to establish fees for new items. We identified five main categories upon which new DMEPOS items can be compared to older DMEPOS items: Physical components; mechanical components; electrical components (if applicable); function and intended use; and additional attributes and features.

As shown in Table 12, a comparison can be based on, but not limited to, these five main components and various attributes falling under the five main components. When examining whether an item is comparable to another item, the analysis can be based on the items as a whole or its subcomponents. A new product does not need to be comparable within each category, and there is no prioritization of the categories. The attributes listed in Table 12 under the five main components are examples of various attributes CMS evaluates within each category. We believe that establishing a framework and basis for identifying comparable items in regulation would improve the transparency and predictability of establishing fees for new DMEPOS items.

TABLE 12—COMPARABLE ITEM ANALYSIS

[Any combination of, but not limited to, the categories below for a device or its subcomponents]

Components	Attributes
Physical Components	Aesthetics, Design, Customized vs. Standard, Material, Portable, Size, Temperature Range/Tolerance, Weight.
Mechanical Components	Automated vs. Manual, Brittleness, Ductility, Durability, Elasticity, Fatigue, Flexibility, Hardness, Load Capacity, Flow-Control, Permeability, Strength.
Electrical Components	Capacitance, Conductivity, Dielectric Constant, Frequency, Generator, Impedance, Piezoelectric, Power, Power Source, Resistance.
Function and Intended Use	Function, Intended Use.
Additional Attributes and Features	''Smart'', Alarms, Constraints, Device Limitations, Disposable Parts, Features, Invasive vs. Non-Invasive.

We believe that by establishing a basis for comparability, stakeholders would be better informed on how these analyses are performed, creating a more transparent process that stakeholders would better understand and which would facilitate a more efficient exchange of information between stakeholders and CMS on the various DMEPOS items and services, both old and new. We believe this would also help avoid situations where comparable DMEPOS items have vastly different fee schedule amounts or where items that are not comparable have equal fee schedule amounts.

2. Sources of Pricing Data Other Than Fees for Comparable Items

We also reviewed the concerns about our process for establishing payment amounts for new DMEPOS item and services when CMS is establishing the fee schedule amount for a new item that lacks a Medicare pricing history and CMS is unable to identify comparable items with existing fee schedule amounts (84 FR 38374). In these cases, other sources of pricing data must be used to calculate the DMEPOS fee schedule amount for the new item.

Current program instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual set forth a process for obtaining the main source of pricing data when establishing the fee schedule amount for a new item that lacks a Medicare pricing history. The instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual specify that supplier price lists may be used in these cases, and that supplier price lists can include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. In 2018, we clarified in the instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual that potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data. Our rationale for using supplier price lists for gap-filling purposes is that supplier price lists provide the best estimate of what suppliers would have routinely charged for furnishing DMEPOS items during the fee schedule base period (if reasonable charge data for the new item is not available and comparable items with existing fee schedule amounts are not identified). When using supplier price lists to estimate what reasonable charge amounts would have been during the base period, CMS deflates the prices listed in supplier price lists to the fee schedule base period. For example, section 1834(a)(2)(B) of the Act mandates fee schedule amounts for inexpensive DME items based on the average reasonable charges for the item(s) from July 1, 1986 through June 30, 1987. If supplier price lists are used to estimate what these average reasonable charges would have been during the base period of 1986/87, the 2018 (for example) prices listed in the supplier price lists are converted to 1986/87 dollars by multiplying the 2018 prices by a deflation factor (.439 in this example) that is listed in section 60.3 of chapter 23 of the Medicare Claims Processing Manual. The deflation factor is equal to the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the price is in effect (June of 2018 in this example) to the mid-point of the fee schedule base period (December of 1986 in this example). So, if the 2018 price is $100, this price is multiplied by .439 to compute a 1986/87 price of $43.90. CMS then applies the covered items update factors mandated by section 1834(a)(14) of the Act for use in updating the data from the base period to establish current fee schedule amounts. In the example above, the $43.90 base fee is updated to $66.80 for 2019 if the device is a class II device or

$74.16 if it is a class III device, after applying the update factors mandated by section 1834(a)(14) of the Act.

In the CY 2020 DMEPOS proposed rule (84 FR 38375), we noted that another source of information is a technology assessment. We proposed that technology assessments would be used whenever we believe it is necessary to determine the relative cost of a new DMEPOS item compared to DMEPOS items that CMS paid for during the fee schedule base period. CMS would use these technology assessments to gap-fill fees for the new DMEPOS item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

As a result of our review of the major stakeholder concerns about our process for establishing payment amounts for new DMEPOS items and services involving code or item comparability determinations, we proposed to add provisions to the regulations at §§ 414.110 and 414.236 to codify how CMS and our contractors will make efforts to determine when a new or existing DMEPOS item is comparable and the application of continuity of pricing when items are re-designated from one HCPCS code to another (84 FR 38375). Also as a result of our review of the major stakeholder concerns about our process for establishing payment amounts for new DMEPOS items and services without a fee schedule pricing history, we proposed to add a provision to the regulations at §§ 414.112 and 414.238 to establish main categories of components or attributes of DMEPOS items that would be evaluated to determine if a new item is comparable to older existing item(s) for gap-filling purposes. If it is determined that the new item is comparable to the older existing item(s), we proposed to use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. We also proposed that if it is determined that there are no comparable items to use for gap-filling purposes and other sources of pricing data must be used to calculate the DMEPOS fee schedule amount for the new item, the fee schedule amounts for a new item would generally be based on supplier or commercial price lists, deflated to the fee schedule base period and updated by the covered item update factors. If supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, we proposed to use technology assessments that determine the relative costs of the newer DMEPOS items compared to older DMEPOS item(s) to establish the fee schedule amounts for the newer DMEPOS items (84 FR 38375).

3. Timing of Fee Schedule Calculations and Interim Pricing

In some cases, HCPCS codes for new DMEPOS items may take effect before the DMEPOS fee schedule amounts have been calculated and added to the national DMEPOS fee schedule files. In these cases, the DME MACs and other contractors establish interim local fee schedule amounts in order to allow for payment of claims in accordance with fee schedule payment rules. Also, instructions for the implementation of interim fees may be released along with other updates to the national DMEPOS fee schedule files on a quarterly basis, along with any corrections of errors made in calculating fee schedule amounts (see section 60.2 of chapter 23 of the Medicare Claims Processing Manual). Changes to fee schedule amounts are generally implemented on a quarterly basis to permit preparation and testing of the fee schedule files and claims processing edits and systems.

Also, as explained in section V.B.4 of this final rule, the time period that an interim local fee may be effective for claims payment could be affected by the process used to obtain public consultation and feedback from stakeholders on the establishment of a fee schedule amount for a new item.

4. Public Consultation and Stakeholder Input

Consistent with section 531(b) of BIPA, CMS obtains public consultation on preliminary coding and payment determinations for new DME items and services each year at public meetings held at CMS headquarters in Baltimore, Maryland. These meetings are also held to obtain public consultation on preliminary coding and payment determinations for other DMEPOS items in addition to DME. The public meetings for preliminary coding and payment determinations could be used to obtain public consultation on gap-filling issues such as the comparability of new items versus older items, the relative cost of new items versus older items, and additional information on the pricing of new DMEPOS items. In addition, manufacturers of new items often request meetings with CMS to provide information about their products, and CMS can reach out to manufacturers and other stakeholders for additional information that may be necessary in the future for pricing new DMEPOS items.

5. Pricing Data and Information Integrity

Our concerns about the integrity of the data and information submitted by manufacturers for the purpose of assisting CMS to establish new DMEPOS fee schedule amounts have led CMS to review our process for establishing fee schedule amounts for new DMEPOS items. We have concerns with using supplier invoices and information for commercial pricing such as internet and manufacturer-submitted pricing. Our experience with reviewing manufacturer submitted prices and available information on the internet for new DMEPOS has caused CMS to have the following concerns about using invoices and information for commercial pricing:

- Internet prices may not be available or reliable, especially if the posted price is the manufacturer's suggested price or some other price that does not represent prices that are actually paid in the commercial markets.
- New products are often only available from one manufacturer that controls the market and price.
- Current invoices from suppliers may not represent the entire universe of prices and typically do not reflect volume discounts, manufacturer rebates, or other discounts that reduce the actual cost of the items.
- Prices from other payers may not reflect the unique costs and program requirements applicable to Medicare payment for DMEPOS and may be excessive if they represent the manufacturer suggested retail prices rather than negotiated lower rates.
- If the prices result in excessive payment amounts, it may be difficult to determine a realistic and equitable payment amount using the inherent reasonableness authority or lower the payment amounts by, for example, including the items in a competitive bidding program.
- Using excessive prices to calculate fee schedule amounts for new items would be unfair to manufacturers and suppliers of older, competitor products not priced using the same inflated commercial prices.

Numerous challenges exist including the significant number of sources of pricing information: Medicare Advantage (MA) plans, private insurers, the Veterans Benefits Administration, Tricare, Federal Employee Health Plans,

Medicaid state agencies, internet prices, catalog prices, retail store prices, and other sources. Prices for a particular item or service can vary significantly depending on the source used. If the median price paid by one group of payers (for example, non-Medicare payers) is significantly higher than the median price paid by another group of payers (for example, MA plans), not using or factoring in the prices from the group of payers with the lower prices could result in grossly excessive fee schedule amounts that are then difficult to adjust using the inherent reasonableness authority, which requires numerous time consuming and resource-intensive steps. These are just a few of the reasons why we believe it is always best to use established fee schedule amounts for older items, if possible, and compare those older items to the newer items, rather than using supplier invoices and information for commercial pricing such as internet and manufacturer-submitted pricing to establish the fee schedule amounts for new items.

6. Adjustment of Fees Over Time

We have been consistent in applying the following guidelines once fee schedule amounts have been established using the gap-filling process and included in the DMEPOS fee schedule: (1) Fee schedule amounts are not changed by switching from one gap-filling method (such as using supplier price lists) to another gap-filling method (such as using fees for comparable items); and (2) fee schedule amounts are not changed as new items falling under the same HCPCS code. However, we have revised fee schedule amounts established using the gap-filling process when we determined that an error was made in the initial gap-filling of the fee schedule amounts or when adjustments were made to the fee schedule amounts based on the payments determined under the DMEPOS competitive bidding program. If fee schedule amounts were gap-filled using supplier price lists, and the prices subsequently decrease or increase, the gap-filled fee schedule amounts are not revised to reflect the changes in the prices.

However, we recognize that this gap-filling method of using supplier prices could result in excessive fee schedule amounts in cases where the market for the new category of items is not yet competitive due to a limited number of manufacturers and suppliers. We now believe that if supplier or commercial prices are used to establish fee schedule amounts for new items, and the prices decrease within 5 years (once the market for the new items is more established), that CMS should gap-fill those prices again in an effort to reflect supplier prices from a market that is more established, stable, and competitive than the market and prices for the item at the time CMS initially gap-filled the fee schedule amounts. For example, most DME items furnished during the applicable 1986/87 fee schedule base period, such as wheelchairs, hospital beds, ventilators, and oxygen equipment, were covered by Medicare in 1986/87 and paid for on a reasonable charge basis for many years (20 years in many cases). Thus the fee schedule amounts calculated using average reasonable charges from the 1986/87 fee schedule base period(s) reflected prices from stable, competitive markets. In contrast, new items that are not comparable to older items are often made by one or a few manufacturers, so the market for a new item is not yet stable or competitive, especially as compared to the market for most DMEPOS items that have fee schedule amounts that were established based on reasonable charges during the fee schedule base period. During the various fee schedule base periods such as 1986/87 for DME, prosthetic devices, prosthetics and orthotics, most items had been on the market for many years, were made by multiple competing manufacturers, and were furnished by multiple competing suppliers in different localities throughout the nation. Therefore, the average reasonable charges from the fee schedule base period generally reflect supplier charges for furnishing items in a stable and competitive market.

We believe that if supplier or commercial prices used to gap-fill fee schedule amounts for a new item decrease within 5 years of the initial gap-filling exercise, that the new, lower prices likely represent prices from a more stable and competitive market. We also believe that supplier prices from a stable and competitive market better represent the prices in the market for DMEPOS items covered during the fee schedule base period and therefore are a better proxy for average reasonable charges from a fee schedule base period (as specified in the statute) as compared to supplier or commercial prices when an item is brand new to the market. We believe that gap-filling a second time once the market for the item has become more stable and competitive would result in fee schedule amounts that are more reflective of average reasonable charges for DMEPOS items from the fee schedule base period. We believe CMS should conduct gap-filling the second time within a relatively short period of time after the fees are initially established (5 years) and only in cases where the result of the second gap-filling is a decrease in the fee schedule amounts of less than 15 percent. Thus, if the supplier or commercial prices used to establish fee schedule amounts for a new DMEPOS item decrease by any amount below 15 percent within 5 years of establishing the initial fee schedule amounts, and fee schedule amounts calculated using the new supplier or commercial prices would be no more than 15 percent lower than the initial fee schedule amounts, we believe gap-filling should be conducted a second time to reduce the fee schedule amounts by up to 14.99 percent as a result of using new, lower prices from a more stable and competitive market. We do not believe that a similar adjustment is necessary to account for increases in supplier or commercial prices within 5 years of establishing initial fee schedule amounts since the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time.

Thus we proposed a one-time adjustment to gap-filled fee schedule amounts based on decreases in supplier or commercial prices. The statute requires CMS to establish fee schedule amounts for DMEPOS items and services based on average reasonable charges from a past period of time, generally when the market for most items was stable and competitive. In many cases, fee schedule amounts may be gap-filled using manufacturer prices or prices from other payers for new technology items that may only be made by one manufacturer with limited competition. In these situations, competition from other manufacturers or increases in the volume of items paid for by Medicare and other payers could bring down the market prices for the item within a relatively short period of time after the initial fee schedule amounts are established, creating a more stable and competitive market for the item, we believe that gap-filling using prices from a stable, competitive market is a better reflection of average reasonable charges for the item from the fee schedule base period. While the fee schedule covered item update as described in sections 1834(a)(14), 1834(h)(4), 1834(i)(1)(B), and 1842(s)(1)(B)(ii) of the Act allow for increases to the fees schedule amounts that can address increases in cost of furnishing items and services over time or track increases in supplier or commercial prices, there is no corresponding covered item update that

results in a decrease in fee schedule amounts when the market for a new item becomes more mature and competitive following the initial gap-filling of the fee schedule amounts. We also do not believe that a situation in which prices increase within a short period of time after the item comes on the market and fee schedule amounts are initially established for the item would be common. We therefore did not propose similar one-time increases in fee schedule amounts established using supplier or commercial prices, however, we invited comments on this issue.

We do not believe gap-filling fee schedule amounts for new items should be conducted a second time in situations where the prices decrease by 15 percent or more within 5 years of the initial gap-filling of the fee schedule amounts. In cases where supplier or commercial prices used to establish original gap-filled fee schedule amounts increase or decrease by 15 percent or more after the initial fee schedule amounts are established, this would generally mean that the fee schedule amounts would be grossly excessive or deficient within the meaning of section 1842(b)(8)(A)(i)(I) of the Act. In such circumstances we believe that CMS could consider making an adjustment to the fee schedule amounts in accordance with regulations at § 405.502(g). We can also consider whether changes to the regulations at § 405.502(g) should be made in the future to specifically address situations where supplier or commercial prices change by 15 percent or more and how this information could potentially be used to adjust fee schedule amounts established using supplier or commercial prices.

C. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Proposed Rule

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 38330 through 38421), hereinafter referred to as the ''CY 2020 DMEPOS proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019.

In the CY 2020 DMEPOS proposed rule, we proposed a gap-filling methodology for establishing payment amounts for new DMEPOS items and services and one-time adjustment to gap-filled payment amounts for DMEPOS items and services using supplier or commercial prices in cases where such prices decrease within 5 years. We solicited comments on our proposals and we summarize the comments that we received below. We received approximately 30 comments on these topics from suppliers, manufacturers, and associations or organizations representing suppliers and manufacturers. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the DMEPOS provisions we are finalizing.

The comments and our responses to those comments are set forth below.

Comment: Some commenters expressed appreciation for the detailed explanation of the gap-filling process in the proposed rule.

Response: We appreciate the comments.

Comment: Many commenters supported increased transparency during the process for establishing fee schedule amounts for new or revised HCPCS codes that allows for stakeholder input and consultation on the pricing methodology used as well as sources of data used in establishing the tentative or preliminary fee schedule amounts. Specifically, some commenters suggested that CMS increase transparency by establishing a process for stakeholders to receive information and provide feedback to CMS if they believe that the new HCPCS code should not be paid at the fee schedule amount that CMS is proposing as the result of the addition or subdivision of previous codes. Some commenters recommended CMS's comparability analysis should include a written report that is shared with the public, prior to a final decision on establishing new fee schedule amounts for new items. One commenter recommended simultaneous expansion of the HCPCS Level II Code application to allow applicants to address this specific topic without limiting other important information by virtue of application page limits. In addition, the commenter requested that the public meetings for DMEPOS should also be updated to allow additional presentation time for this information at the discretion of the applicant. Another commenter stated that CMS should also permit an opportunity for stakeholders to show that the pricing that was applicable in the past was established inappropriately or fails to consider technological changes.

Response: We appreciate the support for our proposal to establish a methodology for calculating fee schedule payment amounts for new DMEPOS items and services. Section 531(b) of BIPA mandated the establishment of procedures for coding and payment determinations for new DMEPOS items that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM. We implemented procedures that permit public consultation regarding requests for codes for new DME and also extended these procedures to external requests for codes for all DMEPOS items and services. CMS holds annual public meetings to obtain public consultation on preliminary coding and payment determinations for new DMEPOS, that is, requests for codes for DMEPOS items and services. For more information about the HCPCS public meetings, see *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html*. We believe that stakeholders can use this process to provide input and consultation on sources of information for gap-filling for new DMEPOS items.

Comment: Many commenters recognized that sections of our gap-filling methodology proposal had been available in program guidance and implemented; however, the commenters did not support adding regulations which codify the program guidance. The commenters expressed concern that the methodology may not be appropriate in all situations. Also, some commenters expressed concern that the methodology maintains that the use of gap filling to address more than a 30-year span between the base year of 1986 to 1987 and 2020, which may not be a reasonable methodology to establish current year fee schedule amounts. Several commenters suggested that CMS delay implementation of the DMEPOS proposals by one calendar year to collect further stakeholder input on the appropriate cross-walk categories, comparable item methodology, and procedures.

Response: We believe that the procedures described above for obtaining public consultation on preliminary coding and payment determinations for DMEPOS can be used by stakeholders to provide consultation on sources of information for gap-filling for new DMEPOS items

and other preliminary coding determinations for DMEPOS that might affect pricing of the items under the fee schedule. With regard to the comments regarding the 30-year span between the fee schedule base year of 1986 to 1987 and items furnished in 2020, sections 1834(a) and (h) of the Act specifically require that fee schedule amounts for DME, prosthetics, orthotics, and prosthetic devices be based on average reasonable charges from 1986 and 1987. Sections 1834(a)(14) and 1834(h)(4)(A) of the Act mandate annual updates to the fee schedule amounts established using average reasonable charges from 1986 and 1987, and sections 1842(b)(8) and (9) of the Act provide CMS with the authority and a process for establishing special payment amounts in cases where the fee schedule amounts become grossly excessive or deficient over time, for example, due to changes in technology. Sections 1842(b)(8) and (9) of the Act outline a process for establishing realistic and equitable payment amounts in cases where the fee schedule amounts are not inherently reasonable.

The gap-filling methodology that we proposed is a multi-step process. The proposed regulations at §§ 414.110 and 414.236 address the continuity of pricing when items are re-designated from one HCPCS code to another and for new items without a pricing history. The proposed regulations at §§ 414.112 and 414.238 set forth main categories of components or attributes of DMEPOS items that would be evaluated to determine if a new item is comparable to older existing item(s) for gap-filling purposes. The gap-filling methodology ensures a case by case review is conducted of each item that is assigned a new HCPCS code. Furthermore, as discussed in our proposal (84 FR 38373), we have repeatedly solicited feedback from our stakeholders through past rulemaking (71 FR 25687 through 25689 and 83 FR 57046 through 57047, and in our CY 2020 DMEPOS proposed rule (84 FR 38379)). Our proposed gap-filling methodology enhances predictability of pricing for new items and services and improves transparency as compared to the existing program guidance. We also believe it is important to have regulations addressing the pricing of new DMEPOS to create a firm basis for establishing fee schedule amounts in accordance with the statute. We can consider additional updates through future rulemaking if necessary.

1. Continuity of Pricing When HCPCS Codes Are Divided or Combined

We proposed to add § 414.110 under subpart C for fee schedule amounts for PEN and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office, and § 414.236 under subpart D for DME, prosthetic devices, prosthetics, orthotics, surgical dressings, and therapeutic shoes and inserts to address the continuity of pricing when HCPCS codes are divided or combined. If a DMEPOS item is assigned a new HCPCS code, it does not necessarily mean that Medicare payment on a fee schedule basis has never been made for the item and service described by the new code. For example, Medicare payment on a fee schedule basis may have been made for the item under a different code. We proposed that if a new code is added, CMS or contractors would make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) would be mapped to, or cross walked to the new code(s), to ensure continuity of pricing. Since there are different kinds of coding changes, the way the proposed rule would be applied varies. For example, when the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components would not be higher than the fee schedule amount for the original item. However, when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code would continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code would be established by adding the fee schedule amounts used for the components (that is, the total of the fee schedule amounts for the components as the fee schedule amount for the global code). However, when the codes for several different items are combined into a single code, the fee schedule amounts for the new code would be established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

We solicited comments on these proposals. The comments and our responses to the comments are set forth below.

Comment: Several commenters supported our proposal for continuity of pricing when existing HCPCS codes are divided or combined. One commenter, a national trade association for prosthetics and orthotics, stated that the use of pricing continuity when establishing new fees must be reserved only for those instances where there is a direct relationship between the former HCPCS code(s) and the new HCPCS code(s). The commenter stated failure to ensure that a continuity relationship exists could lead to fee schedule calculations that are either inadequate or excessive for the items represented by the new HCPCS codes.

Response: We thank the commenters. We agree that the use of pricing continuity when establishing new fees must be reserved only for those instances where there is a direct relationship between the former HCPCS code(s) and the new HCPCS code(s). An item must fall within the category of items described by existing codes that are combined or divided in order for the continuity of pricing rules to apply to that item. If an item does not fall under one of the four example categories, then the continuity of pricing rules would not apply. For example, if the code for a cane is divided into codes for red canes, white canes, blue canes, and canes of any color other than red, white, or blue, there is a direct relationship between the former code (cane) and the four new codes, which are all the canes that used to be described by the former code separated into new codes based on color. The direct relationship is also present in the reverse scenario where multiple canes of all different colors are combined into one code for all of the canes that previously fell under the four separate codes. The same is true for global codes for one item versus separate codes for components of an item. If the code for a cane is divided into codes for cane handle, cane staff, and cane tip, there is a direct relationship between the three new codes for the cane handle, cane staff, and cane tip and the old code for cane since the cane handle, cane staff, and cane tip were all three previously combined in the one code for cane. The direct relationship is also present in the reverse scenario where codes for a cane handle, cane staff, and cane tip that describe the components of a cane are combined into a single code for cane.

Comment: Another concern expressed by the commenters is that the proposed continuity of pricing can lock in historical levels of reimbursement when establishing fee schedule amounts for

new items. Commenters explained that if reimbursement levels are arbitrarily depressed due to the consolidation and bifurcation of codes, practitioners will have a financial incentive to provide the patient with the less expensive component in order to make ends meet. Providers should not be placed in this situation, and patients should not be denied access to the technologies with which they may achieve optimal outcomes. Therefore, the commenters urged CMS to recognize differences in separate components or devices when assigning codes, and determine reimbursement levels based on those differences so that patients can gain access to innovative DMEPOS items and services.

Some commenters stated the methodology may discourage manufacturers from innovating and investing in technology that would result in improved patient outcomes and satisfaction. Another commenter representing rehabilitation technology suppliers stated consolidating and splitting codes will have a negative effect on access to necessary technology. The commenter stated the long-term effects for individuals who rely on complex technology requires an increase recognizing that new technology items can result in decreases in hospitalizations, pressure wounds, and other secondary health issues. Thus, the commenter suggested that CMS should instead establish more codes that have a more focused description.

Response: We do not agree. The continuity of pricing proposal addresses combining or dividing existing codes that already describe certain categories of items, for example canes. Canes are inexpensive DME items that were paid on a reasonable charge basis in 1986 and 1987. Section 1834(a)(2) of the Act mandates that the fee schedule amounts for inexpensive and routinely purchased items be based on average reasonable charges from July 1, 1986 through June 30, 1987, increased by annual covered item update factors. Thus, in accordance with the statute, the fee schedule amounts for canes are based on the 1986/87 reasonable charge data. If the code for canes is divided into four codes—one for red canes, one for white canes, one for blue canes, and one for canes of any color other than red, white, or blue, payment for the four new codes for canes would still be made on the basis of the fee schedule (and therefore the 1986/87 reasonable charge data), in accordance with the statute. If technology innovations for canes over time result in a situation where the cost of canes has risen to the point where the fee schedule amounts are grossly deficient, CMS could use the authority and process at sections 1842(b)(8) and (9) of the Act to establish a different fee schedule amount for canes than the one established in accordance with the payment rules under section 1834(a) of the Act. Subdividing the HCPCS code for a DMEPOS item such as canes into more specific items (for example, types or colors of canes) should not result in fee schedule amounts that are based on something other than the payment rules described in section 1834 of the Act.

Comment: Some commenters disagreed with CMS' concern that manufacturer suggested retail prices (MSRPs) are inflated and without merit. The commenter asserted MSRPs should be considered when establishing base prices subject to gap-filling. One commenter recommended that CMS rescind any contractor instruction to discontinue utilizing MSRPs in the gap-filling process.

Response: We have found that manufacturer suggested retail prices are not supplier prices or commercial prices. We therefore do not believe they represent accurate pricing from actual retail markets. We do not believe that MSRPs represent a valid and reliable proxy for supplier charges or market prices for furnishing DMEPOS items. We consider fees for comparable items and verifiable supplier or commercial prices to be better proxies for supplier charges or retail costs than suggestions made by the manufacturer of the product about what the supplier or commercial prices should be for the product. As such, we will not use the MSRP to set the fee schedule rates, and instead, will rely on fees for comparable items and verifiable supplier or commercial prices in an effort to best approximate reasonable charges from the fee schedule base period for the item.

2. Establishing Fee Schedule Amounts for New HCPCS Codes for Items and Services Without a Fee Schedule Pricing History

We proposed to add § 414.112 under subpart C for fee schedule amounts for PEN and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office, and § 414.238 under subpart D for DME, prosthetic devices, prosthetics, orthotics, surgical dressings, and therapeutic shoes and inserts to address the calculation of fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history. We proposed that if a HCPCS code is new and describes items and services that do not have a fee schedule pricing history, the fee schedule amounts for the new code would be established whenever possible using fees for comparable items with existing fee schedule amounts. We proposed that items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. We proposed that if there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code would be established using supplier or commercial price lists or technology assessments if supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

We proposed that if items with existing fee schedule amounts that are comparable to the new item are not identified, the fee schedule amounts for the new item would be established using supplier or commercial price lists. However, we proposed that if the supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, we propose that the fee schedule amounts for the new item would be established using technology assessments. We proposed that supplier or commercial price lists would include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item, which could include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. We proposed that if the only available price information is from a period other than the fee schedule base period, deflation factors would be applied against current pricing in order to approximate the base period price. We proposed that the annual deflation factors would be specified in program instructions and would be based on the percentage change in the CPI–U from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base

period, as calculated using the following formula:

((base CPI–U minus current CPI–U) divided by current CPI–U) plus one

The deflated amounts would then be considered an approximation to average reasonable charges from the fee schedule base period and would be increased by the annual covered item update factors specified in statute for use in updating average reasonable charges from the fee schedule base period, such as the covered item update factors specified for DME at section 1834(a)(14) of the Act. We proposed that, if within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts would be made using the new prices. As a result of the market for the new item becoming more established over time, the new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula. Again, supplier price lists can include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data. We did not propose a similar adjustment if supplier or commercial prices increase by less than 15 percent, but we invited comments on this issue.

We proposed that fee schedule amounts for items and services described by new HCPCS codes without a fee schedule pricing history that are not comparable to items and services with existing fee schedule amounts may also be established using technology assessments performed by CMS and experts who could help determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts. We proposed that a pricing percentage would be established based on the results of the technology assessment and would be used to establish the fee schedule amounts for the new code(s) based on the fee schedule amounts for existing codes. We proposed that technology assessments would be used when we believe it is necessary to determine the relative cost of a new item compared to items that were available during the fee schedule base period and had established fee schedule amounts. We proposed that we would use technology assessments in order to gap-fill fees for the new item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

We solicited comments on these proposals.

Comment: One commenter indicated that a separate gap-filling process is needed for orthotics and prosthetics since the cost of the professional orthotist and prosthetist services are unique to these items.

Response: We do not agree. All DMEPOS items and services will have different costs for services to furnish the item that are unique to one group of items versus another. Gap-filled fee schedule amounts for orthotics and prosthetics based on comparable orthotics and prosthetics accounts for the costs of the professional orthotist and prosthetist services because they are based on historic charges by the orthotists and prosthetists who furnished the devices in 1986/87 and therefore accounted for the cost of all of their services in the charges they submitted to Medicare during that time. Gap-filling fees for orthotics and prosthetics using supplier or commercial prices for orthotics and prosthetics likewise accounts for the costs of the professional orthotist and prosthetist services because they are based on prices established by or paid to the orthotists and prosthetists who furnish the devices and therefore account for the cost of all of the services performed by the orthotists and prosthetists in furnishing the items.

Comment: Some commenters stated that internet and catalog prices do not reflect the costs to suppliers of compliance with the many Medicare requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation, and thereby do not contribute to a reasonable payment level. One commenter recommended that CMS apply a markup percentage to incorporate the various costs of furnishing a new DMEPOS item that are not reflected in internet or catalog prices.

Response: We thank the commenters for their input. As discussed in our CY 2020 DMEPOS proposed rule, our rationale for using supplier price lists for gap-filling purposes is that supplier price lists provide a good estimate of what suppliers would have charged for furnishing DMEPOS items during the fee schedule base period (if reasonable charge data for the new item is not available and comparable items with existing fee schedule amounts are not identified). Retail prices generally include all costs associated with furnishing items directly to the customer, including overhead and all business expenses such as licensure and accreditation, debt collection, credit cards, filing health insurance claims, delivery, set-up, and education. We believe retail prices for furnishing DMEPOS items and services are a good representation of supplier charges for furnishing DMEPOS items and services.

Comment: One commenter recommended that a weighting method should be applied to a median price when establishing a new fee schedule amount. The commenter stated that the proposed methodology does not account for relative quality, durability, clinical preference, and overall market demand for the various items falling under a HCPCS code. The commenters are concerned that newer items within a code are given the same weight in calculating the median deflated price as items with years of history, use, and sizable market share. The commenter recommended that each item in the payment calculation be weighted based on historic market demand.

Response: We do not agree. We proposed to use supplier or commercial prices to establish fee schedule amounts for new items that we determine are not comparable to any existing item(s). Thus, we do not see the need to give certain prices more weight than other prices as long as we believe they are valid prices for the item described by the HCPCS code. We believe the proposed rule provides the flexibility for us to use the combination of supplier or commercial prices we believe best reflects what suppliers would have charged for items during the fee schedule base period.

Comment: Some commenters expressed concern with our proposals at §§ 414.112(c)(1)(i) and (ii) and § 414.238(c)(1)(i) and (ii) for cases when the only available price information is from a period other than the fee schedule base period, deflation factors would be applied against current pricing in order to approximate the base period price and then the pricing amount would be increased by the annual covered item update factors specified in statute to the current year in order to establish a fee schedule amount for a new item. Several commenters expressed concerns that this step results in fee schedule amounts that are too low. Specifically, the commenters stated that CMS has

omitted inflation rate factors for certain years when the statue required a freeze or no update for those years.

Response: The statute mandates that DMEPOS fee schedule amounts be based on the lesser of the actual charge for the item or the average reasonable charges from a specific period in time. As discussed previously, the statute does not describe how to determine the payment amounts for new items for which there is no average reasonable charge data from the base period, so we have established a gap-filling methodology to attempt to calculate fee schedule amounts for new items and services that reflect the requirements under the statute. Sections 1834(a)(14)(L), 1834(h)(4)(xi), and 1842(s)(1)(B)(ii) of the Act generally require that the DMEPOS fee schedule amounts be adjusted annually by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding year reduced by a productivity adjustment. Through gap-filling, CMS can fill the gap in the historic reasonable charge data, apply the fee schedule update factors mandated by the Act, and then establish a fee schedule amount applicable to the year in which the item is furnished. We are finalizing §§ 414.112(c)(1)(i) and (ii) and 414.238(c)(1)(i) and (ii) as proposed.

Comment: Some commenters suggested that CMS extend the preferential treatment it has finalized for devices designated by the FDA as Breakthrough Devices applying for NTAP in the Medicare Hospital Inpatient Prospective Payment System and proposed for transitional device pass-through payments in the Hospital Outpatient Prospective Payment System to DMEPOS devices too. Specifically, if FDA has assigned ''breakthrough'' or ''expedited access'' designation to a device, clears a device under the ''de novo'' pathway, or decides to establish a new category for a device, then CMS should automatically determine that there is no comparable product for that new item on the DMEPOS fee schedule and set payment rates using market based pricing data accordingly.

Response: We do not agree that classification by the FDA for the purpose of approving or clearing devices as safe and effective should in any way dictate whether one device is comparable to another device for the purposes of establishing a fee schedule amount for the device. If we determine that a new DMEPOS item is comparable to an older item, we believe that the prices established for the older item are a good estimate of what suppliers would have charged for the new item.

Comment: Some commenters suggested CMS implement an appeals process after releasing its determinations with respect to whether a new DMEPOS item is comparable to any existing item; if not, whether there is reliable market-based pricing to use in establishing a fee schedule rate; and the findings of any technology assessment performed to adjust the market-based pricing. CMS also should provide its reasoning to support each of these determinations so that the public may assess and provide feedback on that reasoning. In addition, the commenter suggested CMS should establish a timely, formal appeals process that would allow the manufacturer or other interested party to appeal the fee schedule rate based on (a) disagreement that there is a comparable product or the specific comparison that CMS made; (b) disagreement about whether CMS appropriately used (or did not use) market based pricing data; and (c) disagreement about the findings of the technology assessment.

Response: We obtain public consultation on preliminary coding and payment determinations for DMEPOS items at annual public meetings. These meetings can be used by stakeholders to provide consultation on gap-filling for new DMEPOS items and other preliminary coding determinations for DMEPOS that might affect pricing of the items under the fee schedule. Outside these meetings, the public is able to submit written documentation and other information to CMS via written correspondence at any time if they feel that the information should be considered when establishing a fee schedule amount for a DMEPOS item. CMS also meets with manufacturers and stakeholders about establishing fee schedule amounts when requested. In addition, once fee schedule amounts have been established, the public can submit written documentation and other information to CMS at any time if they believe that an error was made in a fee schedule calculation(s) and CMS would evaluate the information and, if necessary, make corrections to the fee schedule amounts.

Comment: Many commenters opposed our proposal to apply a one-time adjustment to fee schedule amounts previously established using supplier or commercial prices to account for decreases in the supplier or commercial price within five years of establishing the initial fee schedule amounts. One commenter asserted this is not balanced for price fluctuations, and that the same price decrease policy should apply to when prices increase, and that CMS should apply the decrease/increase gap fill equitably. One commenter stated that expanding CMS' authority to reduce (but not increase) Medicare fee schedule amounts based on its perception of reduced charges through market competition is unnecessary and exceeds its statutory authority under inherent reasonableness. Also, some commenters noted since 2011, the annual Medicare fee schedule adjustment has been subject to a statutory reduction known as the Productivity Adjustment. The commenter stated that the Productivity Adjustment is intended to account for changes in economic factors which impact supplier and commercial prices.

However, some commenters supported CMS using the current inherent reasonableness process to adjust pricing—either downward or upward—if the fee schedule level for a particular DMEPOS item or service is found excessive or grossly deficient compared with supplier or commercial prices.

A few commenters stated that CMS should not presume that a short term pricing decrease is appropriate for all new HCPCS codes, and that CMS should first conduct an analysis and use statistically valid and reliable data to substantiate any reduction of up to 15 percent for a particular item. The commenters stated that statistically valid data means obtaining pricing data from at least three independent sources, and ensuring the process is transparent by disclosing what data it proposes to use to substantiate any pricing decrease, and obtaining public input on whether the data it proposes to use to support a payment decrease is appropriate.

Response: As explained in the CY 2020 DMEPOS proposed rule, if supplier or commercial prices are used to gap-fill fee schedule amounts and these prices decrease within 5 years once the market for the new item has become more mature, we believe it would be appropriate to make a one-time adjustment to the fee schedule amounts as long as the same pricing sources are used and the new prices are not lower than the initial prices by 15 percent or more. CMS has been using supplier or commercial prices to gap-fill fee schedule amounts for DMEPOS items since 1989 and this method of gap-filling has not resulted in barriers to access for these items and services. If the prices decrease over time, we believe they would still be valid and reliable market-based prices representing what suppliers charge for furnishing the items and services. As discussed in our proposal (84 FR 38377), we do not believe that a similar adjustment is necessary to account for

increases in supplier or commercial prices within 5 years of establishing initial fee schedule amounts since the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time. We do not agree that the productivity adjustment would fully address more than very modest decreases in prices as the average adjustment over the past 5 years from 2015 to 2019 has been only 0.5 percent.

Comment: CMS received comments that emphasized concern for the proposed five framework comparison categories in our proposal (84 FR 38374 through 38375) to determine if an item in a new HCPCS code is comparable to items in an existing HCPCS code. Those categories are physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. Commenters stated additional criteria should be added to the comparability (for example, service intensity of the item, value to patient care, professional services, customization, intended population, health economic, digital technologies, service intensity, clinical outcome, and clinical care) and the focus of each criterion should be weighted. However, many commenters stated that in order to be considered comparable an item should be interchangeable. Some expressed concern that CMS and/or contractors do not have the required expertise to understand and evaluate technology's inherent relative complexities and costs. That manufacturers, stakeholders, and beneficiaries should have a say in final pricing. On the other side, CMS received comments that supported the transparency of the five categories of used to determine comparability and support of not having a weighted prioritization.

Response: We appreciate the input from the commenters on the proposed five framework comparison categories for determining whether a new item is comparable to items with existing fee schedule amounts. We believe the five categories capture the main categories that should be considered. We would compare all attributes and features that impact the cost of the items, such as service intensity of the item and all services associated with furnishing the item, customization of the item, intended population or intended use, and digital technologies. An evaluation and comparison of attributes that do not impact a supplier's cost for furnishing an item, such as value to patient care, would likely not be necessary in determining whether items are comparable for pricing purposes.

Comment: Many commenters expressed concerns about the use of technology assessments for use in establishing fee schedule amounts for new DMEPOS items. The commenters stated that our proposal (84 FR 38374 through 38375) lacked sufficient details on how the technology assessment process would work and what impact it might have on payment for DMEPOS items and services. The commenters stated a technology assessment is a complicated process and requires the expertise of engineers and others to understand technology's inherent relative complexities and costs. The commenters asserted that even a third party would not be able to break down the costs of a device to understand its production and related costs. Some commenters stated that technology assessments would fail to account for changes in manufacturing (for example, direct and indirect labor, material and equipment, taxes, and shipping costs).

Response: We appreciate the feedback from our stakeholders and we are not finalizing §§ 414.110(d) and 414.238(d) in order to have the opportunity to consider additional information on the use of technology assessments in the gap-filling methodology for DMEPOS items and services. We will consider whether to include a revised proposal addressing the use of technology assessments in gap-filling in future rulemaking. Even so, if supplier prices are not available, we would not use a manufacturer's suggested price for their own product to gap-fill the fees. We would use information from the comparability analysis and any other pricing information that is available to establish the fee schedule amount so that it best reflects what the 1986/87 supplier charges for the item would have been if the item were on the market during the fee schedule base period.

Final Rule Action: After consideration of comments received on the CY 2020 DMEPOS proposed rule and for the reasons we set forth previously in this final rule, we are finalizing §§ 414.110 and 414.236 as proposed. In addition, we are finalizing §§ 414.112 and 414.238 as proposed, with the exceptions of §§ 414.112(d) and 414.238(d), which outlined a process for using technology assessments to establish the fee schedule amounts for new DMEPOS items.

VI. Standard Elements for a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order; Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

A. Background

The Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Improper Payments Information Act of 2002 (IPIA) (Pub. L. 107–300), as amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111–204), as updated by the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (Pub. L. 112–248). As stated in the CERT 2018 Medicare FFS Supplemental Improper Payment Data report, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims had an improper payment rate of 35.5 percent, accounting for approximately 8.2 percent of the overall Medicare FFS improper payment rate.[43]

The Department of Health and Human Services Office of Inspector General (HHS–OIG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness in the programs and operations of the HHS. HHS–OIG's mission is to protect the integrity of HHS programs and is carried out through a network of audits, investigations, and inspections.

The Government Accountability Office (GAO) audits the Centers for Medicare & Medicaid Services' (CMS') operations to determine whether federal funds are being spent efficiently and effectively, as well as to identify areas where Medicare and other CMS programs may be vulnerable to fraud and/or improper payments.

A number of HHS–OIG and GAO reports have focused on waste, fraud, and abuse within the DMEPOS sector. In an effort to reduce improper payments, CMS has issued regulations and sub-regulatory guidance to clarify the payment rules for Medicare DMEPOS suppliers rendering items and submitting claims for payment.

Currently, the scope of payment for medical supplies, appliances, and

[43] 2018 Medicare Fee-for-Service Supplemental Improper Payment Data: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/2018Medicare-FFSSupplementalImproperPaymentData.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.* Accessed September 4, 2019.

devices, including prosthetics and orthotics, are defined at 42 CFR 410.36(a) and the scope and certain conditions for payment of durable medical equipment (DME) are described at § 410.38. Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. These conditions of payment vary by item, but are specified in statute and in our regulations. They are further detailed in our manuals and in local and national coverage determinations.

The purpose of this rule is to simplify and revise conditions of payment aimed at reducing unnecessary utilization and aberrant billing for items described in § 410.36(a) and § 410.38. To avoid differing conditions of payment for different items paid under the DMEPOS Fee Schedule, we proposed the conditions of payment described in proposed § 410.38(d), would also be applied to items specified under § 410.36(a).

1. Face-to-Face and Prescription Requirements for Power Mobility Devices (PMDs)

Section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), in part, added conditions of coverage specific to power mobility devices (PMDs) in section 1834(a)(1)(E)(iv) of the Social Security Act (the Act), that specify payment may not be made for a covered item consisting of a motorized or power wheelchair unless a physician (as defined in section 1861(r)(1) of the Act), physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) (as such non-physician practitioners are defined in section 1861(aa)(5) of the Act) has conducted a face-to-face examination of the individual and written a prescription for the item.

On April 5, 2006, we published a final rule in the **Federal Register** titled ''Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles'' (71 FR 17021), hereinafter referred to as ''April 2006 final rule,'' to implement the requirements for a face-to-face examination and written prescription in accordance with the authorizing legislation. In § 410.38(c)(2)(ii), we required that prescriptions for PMDs must be in writing, signed and dated by the treating practitioner who performed the face-to-face examination, and received by the supplier within 45 days after the face-to-face examination. The April 2006 final rule mandated that the supplier receive supporting documentation, including pertinent parts of the beneficiary's medical record to support the medical necessity for the PMD, within 45 days after the face-to-face examination. It provided that the PMD prescription must include a 7-element order composed of—(1) the beneficiary's name; (2) the date of the face-to-face examination; (3) the diagnoses and conditions that the PMD is expected to modify; (4) a description of the item (for example, a narrative description of the specific type of PMD; (5) the length of need; (6) the physician or treating practitioner's signature; and (7) the date the prescription is written.

2. Face-to-Face and Prescription Requirements for Specified DMEPOS

Section 6407 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) amended section 1834(a)(11)(B) of the Act, which already required a written order, to also require that a physician, PA, NP, or CNS have a face-to-face encounter with the beneficiary within a 6-month period preceding the written order for certain DMEPOS, or other reasonable timeframe as determined by the Secretary of the Department of Health and Human Services (the Secretary).

On November 16, 2012, we published a final rule with comment period in the **Federal Register** titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013'' (77 FR 68892) hereinafter referred to as ''November 2012 final rule,'' that established a list of DME items subject to the face-to-face encounter and written order prior to delivery requirements as a condition of payment. CMS selected items for this initial list based on an item having met one of the following four criteria: (1) Items that required a written order prior to delivery per instructions in the Medicare Program Integrity Manual (at the time of rulemaking); (2) items that cost more than $1,000 (at the time of rulemaking in 2012); (3) items CMS, based on experience and recommendations from the DME MACs, believed were particularly susceptible to fraud, waste, and abuse; and (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the OIG, GAO, or other oversight entities.

Section 504 of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) amended section 1834(a)(11)(B)(ii) of the Act to eliminate the requirement that only physicians could document face-to-face encounters, including those conducted by NPs, PAs, or CNSs. In effect, this change in the law permits NPs, PAs, or CNSs to document their face-to-face encounter, without the co-signature of a physician. For the purpose of this rule, we use the term ''practitioner'' as an all-inclusive term to capture physicians and non-physician practitioners (that is, NPs, PAs, and CNSs).

Section 1834(a)(11)(B)(ii) of the Act, as amended by section 504 of MACRA, mandates that the Secretary require for certain items of DMEPOS (as identified by the Secretary) a written order pursuant to a physician, a PA, an NP, or a CNS (as these three terms are defined in section 1861 of the Act) documenting that such a physician, PA, NP, or CNS has had a face-to-face encounter (including through use of telehealth under section 1834 (m) of the Act and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

Prior to this rule, the regulation at § 410.38(g)(4) required written orders for certain specified covered items, as selected per the regulatory instruction in § 410.38(g)(2), to contain 5 elements: (1) The beneficiary's name; (2) the item of DME ordered; (3) the signature of the prescribing practitioner; (4) the prescribing practitioner National Provider Identifier (NPI); and (5) the date of the order.

3. Subregulatory Requirements for Orders and Face-to-Face Encounters for Other DMEPOS

CMS through subregulatory guidance developed standards for orders for DMEPOS items not included on the list of specified covered items requiring a written order prior to delivery and a face-to-face encounter. In addition, certain items of DMEPOS require face-to-face encounters in item-specific coverage requirements, such as those in the MAC-developed local coverage determinations.

4. Prior Authorization

The Medicare Prior Authorization of PMDs Demonstration was initially implemented in 2012 in 7 states and subsequently extended in 2014 to 12

additional states (for 19 states in total) until its completion in August of 2018. For additional information about this demonstration, see the notice we published in the **Federal Register** on August 3, 2012 (77 FR 46439).

Based on early signs of the demonstration's promising results, on December 30, 2015 we published a final rule in the **Federal Register** titled ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (80 FR 81674), hereinafter referred to as the ''December 2015 final rule,'' that established a permanent prior authorization program nationally. The December 2015 final rule was based on the authority outlined in section 1834(a)(15) of the Act, which permits the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Specifically, the December 2015 final rule established a new provision at § 414.234 that specified a process for the prior authorization of DMEPOS items. The provision interpreted ''frequently subject to unnecessary utilization'' to include items on the DMEPOS fee schedule with an average purchase fee of $1,000 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U)) or greater, or an average rental fee schedule of $100 (adjusted annually for inflation using CPI–U) or greater, that also met one of the following two criteria: (1) The item has been identified as having a high rate of fraud or unnecessary utilization in a report that is national in scope from 2007 or later, as published by the OIG or the GAO; or (2) the item was listed in the 2011 or later CERT program's Annual Medicare FFS Improper Payment Rate DME and/or DMEPOS Service Specific Report(s). In addition, § 414.234(b) lists DMEPOS items that met these criteria on a ''Master List of Items Frequently Subject to Unnecessary Utilization.'' Placement on the Master List makes an item eligible for CMS to require prior authorization as a condition of payment. That regulation instructed CMS to select items from the Master List to require prior authorization as a condition of payment and to publish notice of such items in the **Federal Register**. We stated that items on the Master List would be updated annually, based on payment thresholds and changes in vulnerability reports, as well as other factors described in § 414.234.

We noted in the proposed rule (84 FR 38380) that burden estimates associated with prior authorization are related to the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the contractor for medical review. Prior authorization does not change documentation requirements specified in policy or who originates the documentation. The associated information collection (OMB Control number 0938–1293) was revised and OMB approved the revision on March 6, 2019.

5. Overview

Over time, the implementation of the aforementioned overlapping rules and guidance may have created unintended confusion for some providers and suppliers and contributed to unintended noncompliance. We continue to believe that practitioner involvement in the DMEPOS ordering process, through the face-to-face and written order requirements, assists in limiting waste, fraud, and abuse. We believe practitioner involvement also helps to ensure that beneficiaries can access DMEPOS items to meet their specific needs. In addition, we maintain that the explicit identification of information to be included in a written order/prescription, for payment purposes, promotes uniformity among practitioners and precision in rendering intended items. It also supports our program integrity goals of limiting improper payments and fraudulent or abusive activities by having documentation of practitioner oversight and standardized ordering requirements. Likewise, prior authorization supports ongoing efforts to safeguard beneficiaries' access to medically necessary items and services, while reducing improper Medicare billing and payments. This is important because documentation of practitioner involvement, including their orders for DMEPOS items and documented medical necessity (as assessed under prior authorization), are all used to support proper Medicare payment for DMEPOS items.

This final rule streamlines the existing requirements and reduces provider or supplier confusion, while maintaining the concepts of practitioner involvement, order requirements, and a prior authorization process. We believe streamlining our requirements furthers our efforts to reduce waste, fraud, and abuse by promoting a better understanding of our conditions of payment, which may result in increased compliance.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Proposed Rule

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 38330 through 38421), hereinafter referred to as the ''CY 2020 DMEPOS proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that rule, we proposed technical corrections; updates to definitions and documentation requirements; standard elements of a DMEPOS order; the creation of and inclusion factors for the ''Required Face-to-Face Encounter and Written Order Prior to Delivery List''; and authority to suspend face-to-face encounter and written order prior to delivery requirements at § 410.38. In addition, we proposed to establish a ''Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements'' (the ''Master List''); revisions to the factors for placing an item on the Required Prior Authorization List; and the authority to exempt compliant suppliers at § 414.234. We received approximately 29 public comments on our proposals, including comments from suppliers, practitioners, professional supplier organizations, electronic record vendors, beneficiary advocacy organizations and health care systems.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing.

1. Technical Corrections to § 410.38(a) and (b).

We proposed to make technical changes to § 410.38 by adding headings for paragraphs (a) and (b), and to update obsolete language under paragraph (a). For paragraphs (a) and (b), we proposed the headings as ''General scope'' and ''Institutions that may not qualify as the patient's home,'' respectively. Paragraph

(a) addresses the general scope of the DME benefit, but includes outdated language related to the Medicare payment rules for DME, which are more appropriately addressed under §§ 414.210 and 414.408. In addition, the terms ''iron lungs'' and ''oxygen tents'' refer to obsolete DME technology that is no longer in use. We therefore proposed to revise § 410.38(a) to remove language related to payment rules for DME and to replace the terms ''iron lungs'' and ''oxygen tents'' with ''ventilators'' and ''oxygen equipment,'' respectively.

We received comments on the technical corrections to § 410.38(a) and (b), and our responses are below.

Comment: Some commenters supported CMS' proposal to modernize regulations through the removal of outdated language related to the Medicare payment rules for DME, including the terms ''iron lungs'' and ''oxygen tents.''

Response: We appreciate the commenters support of our proposal.

Final Rule Action: We are finalizing the changes to § 410.38 by adding headings for paragraphs (a) and (b), and by updating obsolete language in paragraph (a).

2. Definitions

We proposed to update § 410.38(c) to include definitions related to certain requirements for the DMEPOS benefit.

We proposed to add new definitions, redesignate existing definitions within the regulatory text, and amend existing definitions. We shared our belief that these changes would promote transparency and create uniform definitions applicable across the DMEPOS benefit and consequently, increase understanding of DMEPOS payment requirements, and may result in increased compliance.

We proposed at § 410.38(c) to include the following terms:

- Physician means a practitioner defined in section 1861(r)(1) of the Act. We proposed this definition as paragraph (c)(1) and we noted that it is the same as our current definition of ''physician'' in § 410.38.
- Treating practitioner means both physicians, as defined in section 1861(r)(1) of the Act, and non-physician practitioners (that is, PAs, NPs, and CNSs) defined in section 1861(aa)(5) of the Act. This definition is consistent with the practitioners permitted to perform and document the face-to-face encounter pursuant to section 1834(a)(11)(B) of the Act. We proposed this definition as paragraph (c)(2).
- We proposed that a DMEPOS supplier means an entity with a valid Medicare supplier number that furnishes durable medical equipment prosthetics orthotics and/or supplies including an entity that furnishes these items through the mail. We proposed this definition as paragraph (c)(3).
- We proposed that a written order/prescription means an order/prescription that is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS. We proposed that all DMEPOS items require a written order/prescription to be communicated to the supplier prior to claim submission. In the case of items appearing on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we proposed that the written order/prescription must additionally be communicated to the supplier before the delivery of the item. As discussed further below, we also noted our intent to standardize the elements of written orders/prescriptions provided for DMEPOS. We proposed this definition as paragraph (c)(4).
- We proposed that a face-to-face encounter means an in-person or telehealth encounter between the treating practitioner and the beneficiary. As discussed further below, we also noted our intent that the face-to-face encounter be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered. We also noted our intent to standardize the face-to-face and documentation requirements for certain DMEPOS. We proposed this definition as paragraph (c)(5).
- We proposed to maintain the definition of a Power Mobility Device (PMD), which is a covered item of DME that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home. Section 410.38(c)(1) required reformatting to accommodate the proposed unified conditions of payment and therefore, we proposed this definition as paragraph (c)(6).
- We proposed that the Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, referred to as the ''Master List,'' means items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list were specified in proposed § 414.234(b). We stated the Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List. We proposed this definition as paragraph (c)(7).
- We proposed that the Required Face-to-Face Encounter and Written Order Prior to Delivery List means a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery, and communicated to the public via a 60-day **Federal Register** notice. When selecting items from the Master List for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we proposed that CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis (for example, comparing the cost of review versus the anticipated amount of improper payment identified), emerging trends (for example, billing patterns, medical review findings,) vulnerabilities identified in official agency reports, or other analysis. We proposed this definition as paragraph (c)(8). We noted that the Required Face-to-Face Encounter and Written Order Prior to Delivery List is distinct from the ''Required Prior Authorization List.''

We received comments regarding our proposal to update § 410.38(c) to include definitions related to certain requirements for the DMEPOS benefit. The comments and our responses are set forth below.

Comment: Some commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. Various commenters suggested we increase the notification period to more than 60 days.

Response: We agree that in some cases, a longer notification timeframe may be appropriate. For example, if we choose to require prior authorization for an item that is very similar to an item already subject to prior authorization, we may choose a shorter notice period, while we may choose a longer period for items that require more substantial education and changes in practice to put into operation. We believe similar types of considerations are appropriate in relation to the face-to-face encounter and written order prior to delivery requirements. Therefore, we are revising the public notice process to allow for longer notification timeframes so that Required Face-to-Face Encounter and Written Order Prior to Delivery List would become effective no less than 60

days after a **Federal Register** notice publication and CMS website posting.

Final Rule Action: We are revising the 60-day public notice timeframe listed in the Required Face-to-Face Encounter and Written Order Prior to Delivery List definition to state ''The list of items is published in the **Federal Register** and posted on the CMS website. The list is effective no less than 60 days following its publication.'' All other definitions will be finalized as proposed.

3. Master List

a. Creating the Master List

In the April 2006 final rule, we established face-to-face examination and written order prior to delivery requirements for PMDs.

In the November 2012 final rule (77 FR 68892), we created a list of Specified Covered Items always subject to face-to-face encounter and written order prior to delivery requirements based on separate inclusion criteria outlined in § 410.38.

In the December 2015 final rule (80 FR 81674), we created a ''Master List of Items Frequently Subject to Unnecessary Utilization'' based on inclusion criteria found at § 414.234 that would potentially be subject to prior authorization upon selection. In the CY 2020 DMEPOS proposed rule, we proposed to create one list of items known as the ''Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements,'' or the ''Master List,'' and specified the criteria for this list in § 414.234.

In the CY 2020 DMEPOS proposed rule, we shared our belief that our proposed changes would harmonize the resultant three lists created by the former rules and develop one master list of items potentially subject to prior authorization and/or the face-to-face encounter and written order prior to delivery requirement. We further explained, in determining DMEPOS appropriate for inclusion in the Master List, our belief that there are inherent similarities in those items posing vulnerabilities mitigated by additional practitioner oversight (face-to-face encounters and written orders prior to delivery) and those items posing vulnerabilities mitigated by prior authorization. Therefore, we proposed that the Master List would include both those items that may potentially be subject to the face-to-face encounter and written order prior to delivery requirements as conditions of payment upon selection, and those items that may potentially be subject to prior authorization as a condition of payment upon selection. (See Table 13: Master List Of DMEPOS Items Potentially Subject to a Face-To-Face Encounter and Written Order Prior To Delivery and/or Prior Authorization Requirements.) We noted that prosthetic devices and orthotic and prosthetic items have the same requirements under section 1834(a)(11) of the Act as other items of DME have in statute. Section 1834(h)(3) of the Act requires that section 1834(a)(11) of the Act apply to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of DME. Therefore, we proposed the items identified in § 410.36(a) would be subject to the requirements identified in proposed § 410.38.

While the regulatory requirements used to create the resultant three lists (outlined in the April 2006, November 2012, and December 2015 final rules) were inherently distinct and conformed to different statutory mandates, we nonetheless assessed the items captured by those individual lists to determine whether the items are included in the new proposed inclusion criteria and resultant Master List. We compared the proposed Master List to both those items of DME that require a face-to-face encounter and written order prior to delivery due to (i) the statutory requirements for all PMDs or (ii) the list of specified covered items of DME that was established in accordance with section 1834(a)(11)(B) of the Act and the November 2012 final rule. We found that 103 items currently captured as either a PMD or included in the list published in the November 2012 rule would not be included in the proposed Master List. We further identified that there are 306 items potentially subject to a face-to-face encounter and a written order prior to delivery under the proposed Master List that did not require it under the conditions of payment that preceded this regulation. The remainder of items on the proposed Master List were both subject to a face-to-face encounter and a written order prior to delivery under the conditions of payment that preceded this regulation, and are potentially subject to these conditions of payment per this final rule. All 135 items that were potentially subject to prior authorization under the conditions of payment that preceded this regulation are also included in our proposed Master List. We outlined the inclusion criteria that developed the proposed Master List of 413 items potentially subject to these conditions of payment.

We shared that while the Master List created by the CY 2020 DMEPOS proposed rule (84 FR 38382) would increase the number of DMEPOS items potentially eligible to be selected and added to the Required Prior Authorization list (which requires a technical update to Paperwork Reduction Act Information Collection CMS–10524; OMB–0938–1293,) there is no newly identified burden, no change in the required documentation associated with prior authorization and no plans to exponentially increase the number of items subject to required prior authorization in the near future.

We proposed at § 414.234(b)(1) that items that meet the following criteria would be added to the Master List:

- Any DMEPOS items included in the DMEPOS fee schedule that have an average purchase fee of $500 (adjusted annually for inflation using CPI–U, and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of $50 (adjusted annually for inflation using CPI–U, and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period, that are:

++ Identified as having a high rate of potential fraud or unnecessary utilization in an OIG or GAO report that is national in scope and published in 2015 or later, or

++ Listed in the CERT 2018 or later Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate.

- The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

++ Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment

criteria, from the preceding 12-month period, or

++ exceeding a 30 percent increase in payments for the item from the preceding 12-month period.

• Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

We provided the following hypothetical data patterns, which are not factual, to demonstrate how data would be assessed in coordination with our new criteria for identifying items, subject to aberrant billing patterns and having a lack of explanatory contributing factors, that would be appropriate for inclusion in the Master List:

Example 1: After removing any item for which there are less than 1,000 claims billed or less than $1 million paid from CY 2018, there were $6.2 billion in total payments for all DMEPOS items. There were $5.6 billion in total payments for all DMEPOS items in the prior 12-month period (CY 2017). The percent change in payments between CY 2017 and CY 2018 is 10.7 percent. The doubled percent change is 21.4 percent.

—DMEPOS Item X had $3.2 million in payments in CY 2018 and $2.4 million in payments in CY 2017. This is a 33.3 percent change in payment for DMEPOS Item X. Therefore, Item X would be added to the Master List since it exceeds a 30 percent increase in payments, which is greater than double the percent change of all DMEPOS claim payments, for items that meet the claim and payment criteria (more than 1,000 claims billed or $1 million paid), from the preceding 12-month period.

—DMEPOS Item Y had $17.1 million in payments in CY 2018 and $13.4 million in payments in CY 2017. This is a 27.6 percent change in payment for DMEPOS Item Y. Therefore, Item Y would not be added to the Master List since it is less than 30 percent.

Example 2: After removing any item for which there are less than 1,000 claims billed or less than $1 million paid from CY 2018, there were $6.5 billion in total payments for all DMEPOS items. There were $5.5 billion in total payments for all DMEPOS items in the prior 12-month period (CY 2017). The percent change in payments between CY 2017 and CY 2018 is 18.2 percent. The doubled percent change is 36.4 percent.

—DMEPOS Item X had $20.4 million in payments in CY 2018 and $14.3 million in payments in CY 2017. This is a 42.7 percent change in payment for DMEPOS Item X. Therefore, Item X would be added to the Master List since it exceeds a 36.4 percent increase in payments which is more than double the percent change in payment in the preceding 12-month period, and is greater than 30 percent.

—DMEPOS Item Y had $3.2 million in payments in CY 2018 and $2.4 million in payments in CY 2017. This is a 33.3 percent change in payment for DMEPOS Item Y. Therefore, Item Y does not meet the inclusion criteria since it is less than 36.4 percent or double the percent change in payment in the preceding 12-month period.

The proposed criteria adheres to the statutory language in section 1834(a)(11)(B) of the Act, which allows us to specify covered items for the face-to-face and written order prior to delivery requirements, and section 1834(a)(15) of the Act, which provides discretion for the Secretary to develop and periodically update a list of items that on the basis of prior payment experience, are frequently subject to unnecessary utilization.

We noted that under our proposal, any item that by statute requires a face-to-face encounter, a written order prior to delivery, or prior authorization would be added to the Master List and potentially subject to any of these requirements. For example, in accordance with section 1834(a)(1)(E)(iv) of the Act, payment may not be made for motorized or power wheelchairs unless there is a face-to-face encounter and a written order prior to delivery. We stated that motorized and power wheelchairs would therefore also potentially be subject to the prior authorization requirement. We shared our belief that this is appropriate because any item statutorily subject to additional program integrity measures can reasonably be assumed to be ''frequently subject to unnecessary utilization'' (the standard for prior authorization in section 1834(a)(15)) and therefore should be included on the Master List.

In addition, we expressed that proposing criteria based on (1) cost, (2) spending thresholds, and (3) data conveying possible overutilization and/or abuse allows us to more effectively focus our program integrity efforts. While the November 2012 and December 2015 final rules included higher cost thresholds ($1,000 purchase/$100 rental thresholds), we noted that programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items, which is the reason we proposed to lower these cost thresholds. We proposed the $500 purchase/$50 rental thresholds based on analysis of the current fee schedule cost of DMEPOS items when compared with known vulnerabilities. This threshold captures items of known vulnerability, as previously identified and included in the Master List of items potentially subject to prior authorization, while remaining cognizant of the overall impact to DMEPOS items. To select the cumulative threshold, we identified low cost items with a significant cumulative impact on the Trust Fund. We then found that approximately the top 10 items individually account for at least 1.5 percent of DMEPOS allowed costs. We accordingly proposed 1.5 percent to capture the items with the highest allowed amounts, while not creating an overly inclusive list. However, we recognized that item(s) may fail to meet the $500 purchase, $50 rental, or cumulative cost thresholds identified in the CY 2020 DMEPOS proposed rule (84 FR 38383); nonetheless, such items may demonstrate aberrant billing patterns inconsistent with predictable claim volumes.

We proposed to use the CERT Medicare FFS Supplemental Improper Payment Data to identify DMEPOS service-specific rates of improper payments; and the OIG and GAO reports to identify DMEPOS items as having a high rate of fraud or unnecessary utilization. Inclusion of an item in these reports are indications that the item is frequently subject to unnecessary utilization. We recognize that there are inherent delays from the time aberrant billing patterns are identified and the publication of CERT, OIG, and GAO reports. Under our prior regulations, we captured reports dating as far back as 2007; however, we have learned that billing practices may be subject to imminent shifts as a result of changed policies from CMS, new technologies and other emerging trends.

Our objective is to focus on more current data, and in the CY 2020 DMEPOS proposed rule (84 FR 38383), we redefined the timeframe for identifying items in OIG and GAO reports to 2015 or later, in CERT Medicare FFS Supplemental Improper Payment Data reports to 2018 or later, and added a new Master List inclusion criteria to capture current aberrant billing patterns. We believe the Master List is a good representation of those items that may pose risk to the Medicare Trust Funds. In future years, we would apply the new criteria on billing patterns occurring over a 12-month period to allow CMS to be nimble to industry change.

We proposed the identification of aberrant billing patterns to be limited to

those instances in which the total payment is at least 1 million dollars and at least 1,000 claims in a recent 12-month period prior to CMS updating the list annually. This avoids us targeting items with very low payments or very few claims, when considered overall.

We summarize the comments and our responses for the Master List section of this final rule along with our final decisions applicable to this section.

Comment: Several commenters were supportive of CMS' proposal to harmonize the three lists through the creation of one Master List. However, some commenters expressed concern that the extended length of the list was indicative of our intent to prior authorize more frequently, and worried about delays in patient care.

Response: The longer Master List grants the agency the ability to impose conditions of payment to mitigate emerging program integrity vulnerabilities for a wider array of items, but is not indicative of any known plans to widely increase prior authorization. Rather, items would only be moved to the Required Prior Authorization List after consideration of the regulatory factors—including item utilization, cost, and other analyses—and would be subject to a no less than a 60-day notice.

We encourage open communication between the beneficiaries and the practitioners, as well as between practitioners and suppliers to ensure that beneficiaries receive medically necessary items in a timely fashion. If beneficiaries, practitioners, or suppliers are observing or experiencing significant delays in beneficiary access to DMEPOS items, they are advised to call 1–800–MEDICARE to report their specific concerns. We note that this rule requires CMS to consider multiple factors prior to subjecting DMEPOS items to conditions of payment, and grants CMS the authority to suspend such condition of payment or remove DMEPOS items from the required list, as needed.

Comment: Some commenters suggested CMS retain the prior cost thresholds ($1,000 purchase price/$100 rental price) for inclusion on the Master List.

Response: We noted in the preamble that the November 2012 and December 2015 final rules included higher cost thresholds ($1,000 purchase/$100 rental thresholds). Programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items, which is the reason we proposed to lower these cost thresholds. We considered known vulnerabilities impacting DMEPOS items, and the item costs listed on the DMEPOS fee schedule prior to selecting the $500 purchase/$50 rental thresholds.

Comment: Some commenters questioned the methodology for inclusion on the list and requested greater transparency in identifying how an item was selected for inclusion. For example, some commenters suggested that CMS increase its percentage threshold for identifying an item's Medicare expenditures, in relation to Medicare expenditures for all DMEPOS items over a recent 12-month period, from 1.5 percent to 2.0 percent. Commenters also questioned the inclusion of certain HCPCS codes on the list. For example, a commenter questioned which criteria applied to HCPCS code A4351—intermittent urinary catheter.

Response: While we appreciate stakeholder feedback on the inclusion criteria, we are not adopting changes at this time. The criteria were based on analysis of our data and consideration of known vulnerabilities and burden. We continue to believe the proposed criteria are most appropriate. While items may meet multiple factors for inclusion, items are only added to the list if they meet one of the inclusion criteria. Due to the varying inclusion criteria, the potential for items to meet multiple factors, and the ever evolving nature of the list, we do not believe it's feasible to maintain a current list that also identifies our underlying reason for inclusion on the list.

We have confirmed the appropriateness of including the HCPCS on the Master List, including those questioned by commenters, based on the list inclusion criteria. For example, commenters questioned the inclusion of HCPCS A4351-intermittent urinary catheter on the Master List. Urological supplies appears on the 2018 CERT Medicare FFS Supplemental Improper Payment Data report chart titled ''Top 20 Service Types with Highest Improper Payments: DMEPOS.'' Thus, HCPCS A4351 meets the Master List inclusion criteria both based on cost (1.5 percent of DMEPOS fee schedule expenditure) and based on its identification in a CERT Medicare FFS Supplemental Improper Payment Data report as an item subject to high improper payments.

Comment: One commenter suggested that the application of the face-to-face encounter and written order prior to delivery was inappropriate for prosthetics and orthotics, and therefore, it is inappropriate to create a combined Master List. For example, commenters suggested that many of the Master List codes describe orthoses that typically must be provided to treat an acute injury.

Response: We respectfully disagree that the application of the face-to-face encounter and written order prior to delivery is inappropriate for prosthetics and orthotics. In our proposal, we noted that prosthetic devices and orthotic and prosthetic items have the same requirements under section 1834(a)(11) of the Act as other items of DME have in statute, and therefore we believe their inclusion to be appropriate. Further practitioners typically have face-to-face encounters in order to assess beneficiary's acute injury before ordering the appropriate orthoses. Therefore, we believe the documentation resulting from this face to face encounter does not create any barrier to treating acute injuries.

Comment: One commenter expressed concern that the lowered cost threshold would create undue burden, because it expands the list to include less expensive DMEPOS items and therefore less likely to achieve savings.

Response: We agree with the commenter that a successful program balances both the cost of the item and resources extended to maintain program integrity. However, experience with prior authorization has demonstrated methods of program efficiencies that allow us to look at lower cost items and still be cost effective.

Comment: One commenter stated that the creation of a single master list of HCPCS codes subject to multiple CMS conditions of payment will further confuse providers and beneficiaries.

Response: We believe there are inherent similarities in those items posing vulnerabilities that can be mitigated by additional practitioner oversight (face-to-face encounters and written orders prior to delivery) and those items posing vulnerabilities that can be mitigated by prior authorization. We emphasize that we will maintain separate ''required'' lists that will enable us to select the most appropriate program integrity action. We believe that the dissemination of two separate lists derived from the Master List will decrease provider burden and confusion.

Comment: One commenter suggested that CMS recognize that while some increases in utilization are indicative of abusive behaviors, others are a result of recent innovations and may be appropriate.

Response: While our rule allows us to focus on increased utilization, we specifically note that we would consider contributory factors when selecting items posing vulnerabilities that may be appropriate for application of these

conditions of payment. An example of a contributory factor that may be considered could be innovative or new technologies.

Final Rule Action: After careful consideration of the comments received, we are finalizing the updates to the Master List criteria as proposed. We believe the updates will allow us to appropriately identify and target items posing vulnerabilities to the Trust Funds, to nimbly take action to promote appropriate claim submissions, and to limit improper payments.

b. Notice and Maintenance of the Master List

In § 414.234(b)(2), we proposed that the Master List would be self-updating, at a minimum, annually. We highlighted in our proposal that the ''self-updating'' process would remain unchanged from the prior regulation and would include applying the criteria to items that appear on the DMEPOS FFS payment schedule. That is, items on the DMEPOS Fee Schedule that meet the payment threshold (for monthly rentals, purchases, or cumulative impacts) will be added to the list when the item is also listed in a future CERT, OIG, or GAO reports, and items not meeting the cost thresholds will be added based on findings of aberrant billing patterns (meeting the inclusion criteria in section VI.B.3.a of this final rule) that are not otherwise explained. We noted that we believe the inclusion criteria are capable of capturing more current vulnerabilities. We also noted that the current standard process in which items on the list, expire after 10 years if they have not otherwise been removed. We believe this is an appropriate representation of the time needed to achieve behavioral change (such as compliance with Medicare coverage instructions and the correction of behaviors previously resulting in improper payments) and protect the Medicare Trust Funds. We also clarified that if we identify any item currently on the Master List as being included in a subsequent OIG or GAO report, as having a high rate of fraud or unnecessary utilization, or as having a high improper payment rate in the CERT Medicare FFS Supplemental Improper Payment Data report, the item would be maintained on the Master List for 10 years from the date of the most recent report's publication.

We proposed that all other list maintenance processes specified in § 414.234(b) would be maintained with two exceptions: (1) We proposed to allow the Master List to be updated as needed and more frequently than annually (for example, to address emerging billing trends), and (2) we proposed to make technical changes to the language in § 414.234(b) to reflect the new cost thresholds and report years. We proposed to maintain the process outlined in the December 2015 final rule (80 FR 81674) and publish any additions or deletions to the Master List, for any of the reasons and conditions discussed, in a **Federal Register** notice and on the CMS website.

We did not receive any comments in regards to the maintenance of the Master List section of the final rule, and we are finalizing this section as proposed.

Final Rule Action: We are finalizing our proposal at § 414.234(b)(2) that the Master List would be self-updating, at a minimum, annually. We are also finalizing our proposals related to the application of the 10-year timeframe. We are adopting the technical updates to § 414.234(b), and finalizing our capacity to update the list more frequently than annually, as needed. We will publish any additions or deletions to the Master List, for any of the reasons and conditions discussed, in a **Federal Register** notice and on the CMS website.

4. Required Face-to-Face Encounter and Written Order Prior to Delivery List

a. Creating the Required Face-to-Face Encounter and Written Order Prior to Delivery List

Section 1834(a)(1)(E)(iv) of the Act prohibits payment for motorized or power wheelchairs unless a practitioner conducts a face-to-face examination and writes an order for the item. Section 1834(a)(11)(B) of the Act requires that a practitioner have a face-to-face encounter and written order communicated to the supplier prior to delivery for other specified covered items of DMEPOS, as identified by the Secretary. In the CY 2020 DMEPOS proposed rule (84 FR 38384), we noted the analysis of a 1-year snapshot of claims indicated that approximately 97 percent of beneficiaries receiving DMEPOS had a recent face-to-face encounter (either before or after the DMEPOS date of service). This data was drawn without regard for the item's presence on the DME List of Specified Covered Items (stemming from the November 2012 final rule), which required a face-to-face encounter and a written order prior to delivery. While we believe this information helped to provide important context, we noted that this final rule requires that face-to-face encounters occur prior to the delivery of DMEPOS for those items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. We proposed to revise § 410.38(d)(1) and § 410.38(d)(2) to limit the face-to-face encounter and written order prior to delivery conditions of payment to only those items selected from the Master List and included on the ''Required Face-to-Face Encounter and Written Order Prior to Delivery List.'' We noted in the CY 2020 DMEPOS proposed rule (84 FR 38384) that this provides us with a broader list of potential items that could be selected, but expect only a subset of items from the Master List to be subject to the face-to-face encounter and written order prior to delivery requirements, based on those items identified to be of highest risk. We believe tailoring the lists this way significantly reduces any potential supplier/provider impact and may decrease the number of items affected.

We also noted in the CY 2020 DMEPOS proposed rule (84 FR 38384) that since the face-to-face encounter and written order are statutorily required for PMDs, they would be included on the Master List and the Required Face-to-Face Encounter and Written Order Prior Delivery List in accordance with our statutory obligation, and would remain there. In addition, the Master List would include statutorily-identified items, as well as any other items posing potential vulnerability to the Trust Fund, as identified via the proposed Master List inclusion criteria.

We proposed at § 410.38(c), in the definition of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the factors that we may consider when determining which items may be appropriate to require a face-to-face encounter and written order prior to delivery. Specifically, we proposed to consider: Operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis. We developed factors that we believe to be indicative of the need for the face-to-face encounter and written order prior to delivery requirements, but noted this list is not exhaustive. We also noted that we did not propose an all-inclusive list of factors to account for the fluidity of program operations and associated vulnerabilities, and we believe this is critical to protect beneficiaries, the program, and industry.

We solicited comments on both our underlying presumption that the list should not be exhaustive, as well as the factors we should consider when selecting an item from the Master List and including it on the Required Face-to-Face Encounter and Written Order Prior to Delivery List.

We proposed at § 410.38(c)(5) to define the term ''face-to-face encounter'' as an in-person or telehealth encounter between the treating practitioner and the beneficiary. We further proposed at § 410.38(d)(2) that any telehealth encounter must meet the existing telehealth requirements of § 410.78 and § 414.65. We noted in the CY 2020 DMEPOS proposed rule (84 FR 38384) that under the November 2012 final rule, telehealth services were permitted to be used to satisfy the DME face-to-face encounter requirements. We emphasized in the CY 2020 DMEPOS proposed rule at § 410.38(d)(2) that telehealth services used to meet DMEPOS face-to-face encounter requirements must meet the requirements found at § 410.78 and § 414.65 to support payment of the DMEPOS claim.

Additionally, we specified that the face-to-face encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered and must occur within the 6 months preceding the date of the order/prescription. We proposed to codify at § 410.38(d)(3) that the documentation necessary to support the face-to-face encounter and associated claims for payment includes the written order/prescription and documentation to support medical necessity, which may include the beneficiary's medical history, physical examination, diagnostic tests, findings, progress notes, and plans for treatment. We believe this is reflective of clinical practice and the information necessary to demonstrate medical necessity and the appropriateness of claim payment.

Section 1834(h)(5) of the Act states that for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by orthotists and prosthetists shall be considered part of the individual's medical record to support documentation created by eligible professionals as described in section 1848(k)(3)(B) of the Act. Documentation from a face-to-face encounter conducted by a treating practitioner, as well as documentation created by an orthotist or prosthetist becomes part of the medical records and if the orthotist or prosthetist notes support the documentation created by eligible professionals described in section 1848(k)(3)(B), they can be used together to support medical necessity of an ordered DMEPOS item. In the event the orthotist or prosthetist documentation does not support the documentation created by the eligible professional, CMS may deny payment.

Our regulations currently require that the written order be communicated prior to delivery for certain specified covered items, within 6 months of the face-to-face encounter, and for PMDs, within 45 days of the face-to-face examination. We proposed to revise § 410.38 to apply the 6-month timeframe to all items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List (including PMDs, which previously required a 45-day timeframe) for uniformity purposes. We believe the 6-month timeframe is relevant, and changing it would create unnecessary confusion since the industry has become accustomed to it.

We noted that the 6-month timing requirement does not supplant other policies that may require more frequent face-to-face encounters for specific items. For example, the National Coverage Determination 240.2 titled ''Home Use of Oxygen'' requires a face-to-face examination within a month of starting home oxygen therapy.

We also noted in the CY 2020 DMEPOS proposed rule (84 FR 38385) that we do not believe the requirements for the face-to-face encounter and written order prior to delivery would create any new burdens for the medical review process. The Paperwork Reduction Act Record of Information Collection for medical review (CMS–10417; OMB–0938–0969) covers the burden for responding to documentation requests, generally. Medical review requests require the provider or supplier to submit all documentation necessary to demonstrate compliance with coverage and payment requirements, including the face-to-face encounter.

The comments with regard to the Required Face-to-Face Encounter and Written Order Prior to Delivery List and associated burden, and our responses are set forth below.

Comment: One commenter suggested that CMS add information to the Required Face-to-Face Encounter and Written Order Prior to Delivery List, when items are selected from the Master List, to indicate why items are being subject to a condition of payment.

Response: If an item were chosen to be included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we plan to include narrative information in the **Federal Register** notice explaining why such item is being subject to a condition of payment. We believe this narrative to be most helpful to stakeholder understanding.

Comment: Commenters urged CMS to ensure that the burden of providing face-to-face encounter documentation, used to comply with our statutory requirements and demonstrate medical need, falls upon the beneficiary's treating practitioner and not community pharmacists who may dispense items of durable medical equipment and supplies.

Response: We agree that the beneficiary's practitioner is charged with creating the documentation of the face-to-face encounter. However, we did not propose to amend the longstanding process whereby additional documentation requests are generally sent to the entity requesting Medicare payment.

Comment: Some commenters urged CMS to permit remote patient monitoring using digitally enabled equipment to satisfy the requirement for face-to-face encounters. Another commenter stated that CMS should begin to recognize telemedicine as part of the face-to-face procedure.

Response: We recognize the increasing use of technology to achieve clinical oversight of Medicare beneficiaries. While we believe digitally enhanced items serve a clinical purpose, we note that the face-to-face requirement is required by statute and removing the face-to-face requirement for digitally enhanced items is not within our regulatory purview. The statute allows for the face-to-face encounter to be conducted through use of telehealth in accordance with section 1834(m) of the Act, which sets the requirements for Medicare telehealth services. We explicitly codified that Medicare telehealth services used for meeting the face-to-face encounter requirement when ordering DMEPOS items must meet the existing telehealth requirements of § 410.78 and § 414.65. In this way, documentation submitted to support payment for DMEPOS items that was created based upon a telehealth visit must also meet the requirements for telehealth services to support DMEPOS payment.

Comment: Commenters supported the adoption of the uniform 6-month timeframe in which the face-to-face must occur for written orders prior to delivery.

Response: We appreciate the feedback in support of our proposal of the 6-month uniform timeframes.

Final Rule Action: We are finalizing the process for selecting items from the Master List and factors considered in creating the Required Face-to-Face Encounter and Written Order Prior to Delivery List, as proposed. Items that require a face-to-face encounter and written order prior to delivery, will be included on the Master List and the

Required Face-to-Face Encounter and Written Order Prior Delivery List in accordance with our statutory obligation. We are finalizing our proposal that documentation submitted to support payment for DMEPOS items that was created based upon a telehealth visit must also meet the requirements for telehealth services to support DMEPOS payment. We are also finalizing our documentation requirements as proposed, and the requirement for a face-to-face to occur within 6 months, as proposed.

b. Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List

We proposed at § 410.38(c)(8) that CMS would publish a 60-day **Federal Register** notice and post on the CMS' website any item on the Master List that is selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, which is consistent with our current prior authorization practices for items selected from the Master List of Items Frequently Subject to Unnecessary Utilization and included on the Required Prior Authorization List. Similarly, any DMEPOS item selected from the proposed Master List and included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List would be subject to the face-to-face encounter and written order prior to delivery requirement as a national condition of payment, and claims for those items would be denied if the condition of payment is not met.

We proposed at § 410.38(e) to allow the face-to-face encounter and written order prior to delivery requirements to be nationally suspended by CMS for any items at any time, without undertaking a separate rulemaking, except for those items whose inclusion on the Master List (and subsequently, the Required Face-to-Face Encounter and Written Order Prior to Delivery List) was required by statute. For example, we may need to suspend or cease the face-to-face encounter and written order prior to delivery requirements for a particular item(s) for which we determine the face-to-face encounter and written order prior to delivery requirements are unnecessary to meet our previously described objective of limiting waste, fraud, and abuse. We stated that should we suspend or cease the face-to-face encounter and the written order prior to delivery requirement for any item(s), we would provide stakeholder notification of the suspension on the CMS website.

The comments with regard to the Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, and our responses are set forth below.

Comment: Some commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. Various commenters suggested we increase the notification period to more than 60 days.

Response: As previously stated earlier in this final rule, we agree that in some cases, a longer notification timeframe may be appropriate. As a result, we are revising the 60-day public notice timeframe for the Required Face-to-Face Encounter and Written Order Prior to Delivery List to be effective no less than 60 days after a **Federal Register** notice and CMS website posting.

Comment: Some commenters expressed concern that the face-to-face encounter and written order prior to delivery requirements could inadvertently impede beneficiary access to medically necessary care, and suggested such requirements were inappropriate for certain items such as orthotics and prosthetics.

Response: We believe practitioner involvement assists in reducing waste, fraud and abuse, and also helps to ensure that beneficiaries receive DMEPOS to meet their specific needs. We encourage open communication between the beneficiaries and the practitioners, as well as between practitioners and suppliers to ensure that beneficiaries receive medically necessary items in a timely fashion. Practitioners typically have face-to-face encounters in order to assess the beneficiary's clinical need before ordering DMEPOS items. Therefore, we believe the documentation resulting from this face to face encounter does not create any barrier to treating acute injuries or other clinical needs.

If beneficiaries, practitioners, or suppliers are observing or experiencing significant delays in beneficiary access to DMEPOS due to the imposition of the face-to-face encounter requirement, they are advised to call 1–800–MEDICARE to report their specific concerns.

This rule allows the face-to-face encounter and written order prior to delivery requirements to be nationally suspended by CMS for any items at any time, without undertaking a separate rulemaking, except for those items whose inclusion on the Master List (and subsequently, the Required Face-to-Face Encounter and Written Order Prior to Delivery List) was required by statute. We note that the inclusion of items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List will be monitored for unintended consequences (including beneficiary access concerns).

Final Rule Action: We are revising the 60-day public notice timeframe listed in the Required Face-to-Face Encounter and Written Order Prior to Delivery List to say ''The list of items is published in the **Federal Register** and posted on the CMS website. The list is effective no less than 60 days following its publication.'' We are also finalizing our authority to suspend or cease the face-to-face encounter and written order prior to delivery requirements, with notifications provided on the CMS website, as initially proposed.

5. Required Prior Authorization List

a. Creation and Application of the Required Prior Authorization List

In order to balance minimizing provider and supplier burden with our need to protect the Medicare Trust Funds, we proposed to continue to limit prior authorization to a subset of items on the Master List as currently specified at § 414.234(a)(4). The subset of items requiring prior authorization are referred to as the Required Prior Authorization List.

OIG and GAO reports, as well as the CERT Medicare FFS Supplemental Improper Payment Data reports, provide national summary data and also often include regional data. Utilization trends within Medicare Contractor localities may show aberrant billing patterns or other identifiable vulnerabilities. At times, claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated among certain suppliers or in certain locations or regions. We proposed to select and implement prior authorization of an item(s) nationally or, in collaboration with the medical review contractors locally. We proposed to revise § 414.234(c)(1)(ii) to state that all suppliers (either nationally or within a contractor jurisdiction) would initially be subject to prior authorization for items identified through a **Federal Register** notice and posted to CMS' website. We also proposed that CMS may elect to exempt suppliers demonstrating compliance from prior authorization for such requirements. We noted in our CY 2020 DMEPOS proposed rule (84 FR 38385) that we believe this meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and provider/supplier burden.

In § 414.234, we proposed that we may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends,

vulnerabilities identified in official agency reports, or other analysis in selecting items for national or local implementation. For example, items that are the focus of law enforcement investigations may require additional oversight and be appropriate for prior authorization. Likewise, when assessing cost we may prior authorize low dollar items for which the prior authorization decision is applied to consumables that are the same item, rendered to the same beneficiary (for example, items dispensed in units or billed monthly for which the initial decision would remain appropriate), but would not prior authorize a single low cost item for which the cost of the review would outweigh the anticipated amount of improper payments identified.

We solicited comments on the proposed factors to be considered when selecting an item from the Master List and including it on the Required Prior Authorization List, such as whether the factors could be over-inclusive or under-inclusive.

We noted in the CY 2020 DMEPOS proposed rule (84 FR 38385) that despite the proposed changes in the Master List inclusion criteria, the prior authorization program would continue to apply in all competitive bidding areas because CMS conditions of payment apply under the Medicare DMEPOS Competitive Bidding Program.

We also noted that we recognize that there may be accessories for which stakeholders would like to request prior authorization that may not always appear on the Master List and would not be eligible to include on the Required Prior Authorization List. In addition, we discussed our intent to update the program so that any accessory included on a prior authorization request submitted for an item on the Required Prior Authorization List may nonetheless receive a prior authorization decision for operational simplicity, even if the accessory is not on the Required Prior Authorization List. We stated that the inclusion of such items is voluntary and does not create a condition of payment for items not present on the Required Prior Authorization List. An example of when this occurs is accessories for certain PMDs subject to prior authorization. We stated that the effective date of the final rule may precede shared systems changes that are required to support the addition of accessories that are not on the Master List and the Required Prior Authorization List. Accordingly, there may be a delay in the adoption of this proposed operational change from the date of publication.

We also discussed that historically, we received positive feedback related to the DMEPOS prior authorization process and the majority of comments have been from suppliers. We encouraged all stakeholders, including those representing beneficiaries and Medicare consumer advocacy organizations, to submit their comments about prior authorization during the public comment period.

We proposed that the items currently subject to prior authorization would be grandfathered into the prior authorization program until the implementation of the first Required Prior Authorization List published subsequent to this rule. This proposal would avoid the administrative and stakeholder burdens associated with the termination of the current prior authorization program and the implementation of a revised program created under this rule.

We proposed to retain the documentation requirements for submitting prior authorization requests at § 414.234(d); however, we proposed to cross reference the payment requirements proposed at § 410.38. In addition, we proposed to retain the process for submitting prior authorization requests and receiving responses, but proposed to restructure § 414.234(e) to conform to the formatting of the preceding paragraphs.

We proposed to maintain the authority to suspend or cease the prior authorization requirement generally or for a particular item or items at any time without undertaking a separate rulemaking. For example, we may need to suspend or cease the prior authorization program due to new payment policies, which may render the prior authorization requirement obsolete or remove the item from Medicare coverage. If we suspend or cease the prior authorization requirement, we would publish a notice in the **Federal Register** and post notification of the suspension on the CMS website and include the date of suspension.

The comments with regard to The Required Prior Authorization List, and our responses are set forth below.

Comment: One commenter suggested that CMS add information to the Required Prior Authorization List, when items are selected from the Master List, to indicate why items are being subject to a condition of payment.

Response: As indicated earlier in this final rule, if an item were selected for inclusion in a required list (meaning the Required Prior Authorization List or Required Face-to-Face Encounter and Written Order Prior to Delivery List), we plan to include information in the **Federal Register** notice explaining why an item is being subject to the condition of payment. We believe this information to be most helpful to stakeholder understanding.

Comment: Commenters urged CMS to be cognizant of items that may be needed imminently when selecting items requiring prior authorization.

Response: We consider multiple factors when determining if an item is appropriate for inclusion on the Required Prior Authorization List, including beneficiary access in a timely fashion. We understand the concerns raised by the comments and will take them into consideration. If beneficiaries, practitioners, or suppliers are observing or experiencing significant delays in beneficiary access to DMEPOS due to their inclusion on the Required Prior Authorization List, they are advised to call 1–800–MEDICARE to report their specific concerns.

Comment: One commenter suggested that prior authorization be reserved for aberrant billers, and proposed relief for billers who participate in standardized data collection. Another commenter suggested that CMS consider compliance incentives to waive prior authorizations and face-to-face requirements for providers that meet such standards.

Response: The prior authorization program is item-based and targets over utilized items billed by all applicable suppliers. In the future, we may elect to exempt suppliers demonstrating compliance from prior authorization requirements for subject items. If so, we will define how we will identify compliant suppliers in future rulemaking.

Comment: Some commenters expressed support for continuing the prior authorization process, and appreciated the assurance of likely payment in advance of delivering the item and services that is medically necessary for the beneficiary. Another commenter suggested that prior authorization helps limit appeals and corresponding resources.

Response: We appreciate the commenters' feedback on the prior authorization process.

Comment: One commenter expressed support of CMS' proposal to include in the prior authorization decision for PMDs the accessories that are used with the PMD base. Another commenter expressed concern that prior authorizing accessories for which the base was already prior authorized, may create undue delay in the delivery of care. The commenter was also concerned that the addition of accessories was occurring without formal rulemaking.

Response: We appreciate the commenter's support of our proposal to allow accessories to be included on a prior authorization request, at the supplier's discretion. We emphasize that this is voluntary, and prior authorization of accessories is not a condition of payment. We note that although this voluntary action is being implemented, there will be a delay in implementation until systems changes are made to support the addition of accessories. Regarding supplies, as noted earlier, a prior authorization of supplies will be valid over a period of time and will not require a prior authorization for each subsequent claim submission. These procedural operations will be clarified in subregulatory guidance.

Comment: Commenters expressed concern that supplies be prior authorized at the outset of care, with affirmation decisions being extended across multiple Medicare payments, in order to prevent undue burden and potential interruptions in care.

Response: Claims for subsequent and serial rental items will be covered under the initial prior authorization decision for time periods stated in NCDs, LCDs, statutes, regulations, and CMS issued manuals and publication. For example, if a policy for the subject DMEPOS item requires medical necessity documentation to be updated annually, the initial prior authorization decision will cover the claims for the subject DMEPOS item for 12 months.

Comment: Commenters suggested that if a DMEPOS item is subject to prior authorization and receives an affirmative decision, then by default, the prior authorization would extend to all related options, supplies, and accessories. Likewise, commenters believed the decision on the initial item would support claim payment for future repairs, or should the beneficiary require a same or similar item.

Response: While we are trying to be increasingly cohesive in our prior authorization process, and are implementing changes to voluntarily include accessories, we note that reviewers are limited in their review to the documentation submitted with the request. In addition, we will only make payment for medically necessary items, options, supplies and accessories. Thus, submitted documentation must support the medical necessity of any related options, supplies or accessories. Similarly, if a request for payment is being made for a new replacement item, medical necessity must be established for the replacement.

Comment: Some commenters suggested that prior authorization should not be viewed as a fraud and abuse tool but as an efficiency tool. Commenters suggested that Targeted Probe and Educate (TPE) or other pre-payment audits serve as the primary means of curbing abuse.

Response: While we agree prior authorization creates efficiencies, we note that the statutory construct emphasizes the importance of prior authorization in preventing overutilization before the improper payment occurs. Prior authorization provides assurances to both providers/suppliers and the agency that items or services furnished will likely be covered by Medicare. An affirmation prior authorization decision is provisional because other information that is only available after the claim is submitted may result in a denial. For example, there may be technical issues, such as a duplicate claim, which can only be known only after the claim is submitted.

Final Rule Action: We are finalizing the creation and application process of the Required Prior Authorization List, as proposed.

b. Notice of the Required Prior Authorization List

Section § 414.234 currently requires us to inform the public of items included on the Required Prior Authorization List in the **Federal Register** notice no less than 60 days before implementation. We did not propose any changes to this section. We note that all other prior authorization processes described in § 414.234 not mentioned in this rule remain unchanged.

We believe that it is important that CMS have the authority to require prior authorization for an eligible item(s) (that is, on the Master List) locally to encourage immediate response to shifts in billing patterns, which may be related to potential fraud or abuse, or nationally, as the situation may so dictate. We proposed to maintain our current process, as outlined in § 414.234, and publish a **Federal Register** notice no less than 60 days prior to implementation and post on the CMS website when items are placed on the Required Prior Authorization List.

The comments with regard to the Notice of the Required Prior Authorization List, and our responses are set forth below.

Comment: Some commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. Various commenters suggested we increase the notification period to more than 60 days.

Response: We did not propose any regulatory changes to the notification process for prior authorization, and plan to maintain the regulatory text indicating that the Required Prior Authorization List is effective no less than 60 days after publication and posting. We note that we have granted longer notification periods, to date, in consideration of both the newness of the programs and the types of items selected.

Final Rule Action: We are maintaining our current Notice of the Required Prior Authorization List process, as outlined in § 414.234. When items are placed on the Required Prior Authorization List, we will publish a **Federal Register** notice no less than 60 days before implementation, and post notification on the CMS website.

6. Standardizing the Written Order/Prescription

We note that through subregulatory guidance and the implementation of several regulations, we have adopted different requirements for orders for different items of DMEPOS. To simplify order/prescription requirements and to reduce confusion, we proposed at § 410.38(d)(1) to adopt one set of required written order/prescription elements for all DMEPOS items.

We believe that the process to obtain DMEPOS items is sufficiently similar across the healthcare environment, and that a standardized order requirement is appropriate and would help promote compliance and reduce the confusion associated with complying with multiple, different order/prescription requirements for DMEPOS items. However, we note that the required timing for the order to be provided (from the treating practitioner to the supplier) would continue to vary for DMEPOS items. We proposed at § 410.38(d) that for those items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery of the item (per statutory requirement); for all other DMEPOS items, a written order/prescription must be communicated to the supplier prior to claim submission.

We believe the proposed requirements of the standardized DMEPOS orders/prescriptions are commonly included in orders/prescriptions rendered in clinical practice. We believe consistent requirements for all items would prove useful as electronic vendors develop programs in support of electronic records for provider and supplier use. We proposed at § 410.38(d)(1)(i) that the standardized order/prescription require the elements listed here:

- Beneficiary Name or Medicare Beneficiary Identifier (MBI).
- General Description of the item.
- Quantity to be dispensed, if applicable.
- Date.
- Practitioner Name or National Provider Identifier.
- Practitioner Signature.

Traditionally, these required standardized order elements are written on a prescription/order; however, we recognize that these required elements may be found in the beneficiary's medical record. We proposed at § 410.38(d)(1) that CMS' medical review contractors shall consider the totality of the medical records when reviewing for compliance with standardized order/prescription elements.

While the above standardized elements are conditions of payment, we recognize that additional information might be helpful on the order/prescription for clinical practice and quality of care. Information may be added to the order/prescription or found in the beneficiary's medical records but are not conditions of payment. For example, route of administration—such as whether oxygen is delivered via nasal cannula or face mask is not required as a condition of payment, but may be indicated for good clinical practice.

Current § 410.38(d), (e) and (f) contain written order and documentation requirements specific to equipment that is used for treatment of decubitus ulcers, seat-lifts, and transcutaneous electrical nerve stimulator units. We believe the requirements found at § 410.38(d), (e) and (f) are appropriate for inclusion in the standardized written order/prescription and medical record documentation requirements outlined in the CY 2020 DMEPOS proposed rule. In addition, we believe item-specific coverage requirements may be included in national or local coverage documents, as appropriate. Therefore, we proposed to delete the coverage requirements outlined in § 410.38(d), (e) and (f), and to replace sections § 410.38(d) and (e), with our proposed conditions of payment and process for suspending the face-to-face encounter and written order prior to delivery requirements, respectively.

The comments with regard to standardizing the written order/prescription, and our responses are set forth below.

Comment: We received feedback that the term ''date'' is not sufficiently specific for reviewers and billing entities to know how to date their order/prescription to comply with regulatory and statutory requirements, as applicable. Some commenters supported the uniform order requirements without issue. In particular, one commenter supported the ability to include either the beneficiary name or the Medicare beneficiary identifier (MBI), and either the prescriber name or his/her national provider identifier (NPI), and suggested this policy be adopted for all other Medicare services. One commenter supported the use of the totality of the medical records to document the order/prescription required elements. A commenter reminded CMS that the significant regulatory updates codified in this rule should be reflected and updated in supporting materials.

Response: We appreciate the commenters' support of our proposal to standardize order requirements and the use of the totality of the medical records to document the order/prescription required elements. The comment suggesting that MBI and NPI would be helpful if adopted across all sectors is outside the scope of this rule. Regarding the comment about the date element, we agree with the commenter that the date element may have been subject to interpretation. Accordingly, we will change ''date'' to ''order date''. We will revise its subregulatory guidance to reflect these changes. As noted at § 410.38(d)(1)(ii), a completed order for items on the Required Face-To-Face Encounter And Written Order Prior To Delivery List must occur prior to the item being dispensed. Items not on the list require the order prior to claim submission.

Comment: One commenter requested confirmation whether a standardized order element that is not on the order but is found within the medical record would be considered for payment purposes.

Response: While we believe the basic order requirements imposed by this rule are typical to good clinical practice, we provide reviewers with the capacity to consider the totality of the medical record when a missing or flawed element is clearly documented elsewhere in the record.

Comment: Commenters expressed concern that documentation include quantity to support payment even when the quantity of the item dispensed is one.

Response: We believe the comment is specifically about the written order/prescription included in the documentation required for a face-to-face encounter. As we stated in the CY 2020 DMEPOS proposed rule (84 FR 38379), Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. However, we note ''quantity, as applicable'', is one of the required elements of the order. For many DMEPOS items, the prescription/order will not need to state that ''one'' is the quantity because quantity is not applicable for those items. An example would be a wheelchair. Alternately, a prescription order for disposable supplies will need to include the quantity to be furnished. When reviewing supporting documentation, the reviewer would expect to see clinical need to support any quantity furnished, whether one DMEPOS item or more.

Comment: One commenter suggested that we update the required elements of the standardized order/prescription to specify that ''Practitioner Name or National Provider Identifier (NPI)'' refers to the *treating* practitioner.

Response: We agree with commenter's suggestion. Treating practitioner is consistent with our intent, as defined throughout this final rule. We have updated the written order/prescription section to clarify our intent that the practitioner signing the document and including his or her name be the treating practitioner, as defined throughout § 410.38 (c) and (d). It will now explicitly state ''Treating Practitioner Name or National Provider Identifier (NPI)'' and ''Treating Practitioner Signature.''

Final Rule Action: We are finalizing the order section as proposed in § 410.38(d), with modifications made at § 410.38(d)(1)(i)(D) and § 410.38(d)(1)(i)(E). We are revising the element ''Practitioner Name or National Provider Identifier'' to say ''Treating Practitioner Name or National Provider Identifier (NPI).'' and the element ''Practitioner Signature'' to say ''Treating Practitioner Signature.'' We are also revising the element ''date'' to say ''order date.''

C. Miscellaneous Comments

We received several comments that were outside the scope of the CY 2020 DMEPOS proposed rule. While some of these comments were related to prior authorization topics, they were not the issues we addressed in detail in the proposed rule. In the following discussion, we summarize and respond to the comments.

Comment: Some commenters suggested shortening the procedural timeframes provided to the contractors via operational instructions regarding prior authorization decisions.

Response: The prior authorization operational process is outside the scope

of this final rule, however, we continually strive to make program improvements. After adding an item to the Required Prior Authorization List, we customize final review and decision timelines for each item. In the December 30, 2015 final rule, we stated that this approach to final timelines provides flexibility to develop a process that involves fewer days, as may be appropriate, and allows us to safeguard beneficiary access to care. This is evident in the process developed for the prior authorization of pressure reducing support surfaces, which allows up to 5 days for both initial and resubmitted requests, while prior authorization of PMDs allows up to 10 days for an initial request and 20 days for a subsequent request.

Comment: One commenter urged CMS to allow for more electronic prior authorization communication to further expedite the process for certain items.

Response: The prior authorization operational process is outside the scope of this final rule, however, we continue to discuss with industry about future enhancements to electronic prior authorization processes. Additionally, our medical review contractors have recently started offering prior authorization request submissions and decisions via their online web portals, in efforts to provide suppliers flexibility in communication approaches.

Comment: Some commenters requested CMS clarify that the electronic documentation generated by e-prescribing platforms is an appropriate source of information that can be relied upon during medical reviews.

Response: The format and use of electronic platforms is outside the scope of this rule.

Comment: Commenters suggested that if a beneficiary receives an affirmative prior authorization decision, it should continue to apply even if the beneficiary changes suppliers or moves locations.

Response: We appreciate these comment. Although this suggestion is outside the scope of this regulation, we note that our current processes outlined in our prior authorization operational guides allow for the prior authorization decision and corresponding claim information to remain with the beneficiary. We assume such transfers would be made in accordance with applicable privacy laws.

Comment: Commenters shared their support of the prior authorization process, but expressed concern about the administrative resources needed to effectuate prior authorization requests, which should be reflected in Medicare payments.

Response: We thank the commenters for sharing their concerns. We believe that some assurance of payment and some protection from future audits may ultimately reduce administrative resources. Adjustments to Medicare payments for items subject to prior authorization is outside the scope of this regulation.

Comment: One commenter expressed concern regarding the application of Medicare rules during the audit process, and believes that this ultimately impacts patient care.

Response: We strive to ensure that patients receive the benefits that they are entitled to, while protecting the Medicare Trust Funds against improper payments. The tools that are provided in this rule help limit improper payments. In addition, we believe that the increased communication offered by prior authorization helps ensure suppliers that items furnished are covered by Medicare and provide an assurance of likely payment. We note that we have robust oversight processes in place to ensure the accuracy of medical review and prior authorization decision making thereby avoiding impacts to patient care.

Comment: Some commenters expressed concern that items subject to prior authorization should not be subject to additional audit.

Response: Paid claims for which there is an associated affirmed prior authorization decision will be afforded some protection from future audits. However, when the subject claim falls within the CERT annual sample or when a supplier's billing patterns signal potential fraud, inappropriate utilization or changes in billing patterns, the claim may be subject to an audit.

Comment: Some commenters suggested the face-to-face encounter requirement be eliminated.

Response: We do not have the authority to eliminate the face-to-face encounter requirement since it is statutorily mandated.

Comment: Some commenters requested that CMS initially implement new items to prior authorization within a limited geographic scope, prior to expansion, to ensure a smooth transition to national implementation.

Response: We appreciate the commenters' support of our roll-out processes to date. We will continue to evaluate new items to ensure sufficient timeframes are provided when planning national implementation.

Comment: Some commenters suggested methods to align Part C prior authorization activities with the FFS program, and suggested operational improvements to such programs.

Response: We note that changes to the Medicare Advantage program were not proposed and subject to formal notice and comment under this rulemaking, and are outside the scope of this rule.

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TABLE 13: MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS

HCPCS	Long Description
A4253	Blood Glucose Test Or Reagent Strips For Home Blood Glucose Monitor, Per 50 Strips
A4351	Intermittent Urinary Catheter; Straight Tip, With Or Without Coating (Teflon, Silicone, Silicone Elastomer, Or Hydrophilic, Etc.), Each
A7025	High Frequency Chest Wall Oscillation System Vest, Replacement For Use With Patient Owned Equipment, Each
E0170	Commode Chair With Integrated Seat Lift Mechanism, Electric, Any Type
E0193	Powered Air Flotation Bed (Low Air Loss Therapy)
E0194	Air Fluidized Bed
E0250	Hospital Bed, Fixed Height, With Any Type Side Rails, With Mattress
E0251	Hospital Bed, Fixed Height, With Any Type Side Rails, Without Mattress
E0255	Hospital Bed, Variable Height, Hi-Lo, With Any Type Side Rails, With Mattress
E0256	Hospital Bed, Variable Height, Hi-Lo, With Any Type Side Rails, Without Mattress
E0260	Hospital Bed, Semi-Electric (Head And Foot Adjustment), With Any Type Side Rails, With Mattress
E0261	Hospital Bed, Semi-Electric (Head And Foot Adjustment), With Any Type Side Rails, Without Mattress
E0265	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), With Any Type Side Rails, With Mattress
E0266	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), With Any Type Side Rails, Without Mattress
E0277	Powered Pressure-Reducing Air Mattress
E0290	Hospital Bed, Fixed Height, Without Side Rails, With Mattress
E0292	Hospital Bed, Variable Height, Hi-Lo, Without Side Rails, With Mattress
E0293	Hospital Bed, Variable Height, Hi-Lo, Without Side Rails, Without Mattress
E0294	Hospital Bed, Semi-Electric (Head And Foot Adjustment), Without Side Rails, With Mattress
E0295	Hospital Bed, Semi-Electric (Head And Foot Adjustment), Without Side Rails, Without Mattress
E0296	Hospital Bed, Total Electric (Head, Foot And Height Adjustments). Without Side Rails, With Mattress

HCPCS	Long Description
E0297	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), Without Side Rails, Without Mattress
E0300	Pediatric Crib, Hospital Grade, Fully Enclosed, With Or Without Top Enclosure
E0301	Hospital Bed, Heavy Duty, Extra Wide, With Weight Capacity Greater Than 350 Pounds, But Less Than Or Equal To 600 Pounds, With Any Type Side Rails, Without Mattress
E0302	Hospital Bed, Extra Heavy Duty, Extra Wide, With Weight Capacity Greater Than 600 Pounds, With Any Type Side Rails, Without Mattress
E0303	Hospital Bed, Heavy Duty, Extra Wide, With Weight Capacity Greater Than 350 Pounds, But Less Than Or Equal To 600 Pounds, With Any Type Side Rails, With Mattress
E0304	Hospital Bed, Extra Heavy Duty, Extra Wide, With Weight Capacity Greater Than 600 Pounds, With Any Type Side Rails, With Mattress
E0316	Safety Enclosure Frame/Canopy For Use With Hospital Bed, Any Type
E0371	Nonpowered Advanced Pressure Reducing Overlay For Mattress, Standard Mattress Length And Width
E0372	Powered Air Overlay For Mattress, Standard Mattress Length And Width
E0373	Nonpowered Advanced Pressure Reducing Mattress
E0424	Stationary Compressed Gaseous Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter, Humidifier, Nebulizer, Cannula Or Mask, And Tubing
E0431	Portable Gaseous Oxygen System, Rental; Includes Portable Container, Regulator, Flowmeter, Humidifier, Cannula Or Mask, And Tubing
E0433	Portable Liquid Oxygen System, Rental; Home Liquefier Used To Fill Portable Liquid Oxygen Containers, Includes Portable Containers, Regulator, Flowmeter, Humidifier, Cannula Or Mask And Tubing, With Or Without Supply Reservoir And Contents Gauge
E0434	Portable Liquid Oxygen System, Rental; Includes Portable Container, Supply Reservoir, Humidifier, Flowmeter, Refill Adaptor, Contents Gauge, Cannula Or Mask, And Tubing
E0439	Stationary Liquid Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter, Humidifier, Nebulizer, Cannula Or Mask, & Tubing
E0462	Rocking Bed With Or Without Side Rails
E0465	Home Ventilator, Any Type, Used With Invasive Interface, (For Example, Tracheostomy Tube)
E0466	Home Ventilator, Any Type, Used With Non-Invasive Interface, (For Example, Mask, Chest Shell)
E0470	Respiratory Assist Device, Bi-Level Pressure Capability, Without Backup Rate Feature, Used With Noninvasive Interface, (For Example, Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device))

HCPCS	Long Description
E0471	Respiratory Assist Device, Bi-Level Pressure Capability, With Back-Up Rate Feature, Used With Noninvasive Interface, (For Example, Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device))
E0472	Respiratory Assist Device, Bi-Level Pressure Capability, With Backup Rate Feature, Used With Invasive Interface, (For Example, Tracheostomy Tube (Intermittent Assist Device With Continuous Positive Airway Pressure Device))
E0483	High Frequency Chest Wall Oscillation Air-Pulse Generator System, (Includes Hoses And Vest), Each
E0550	Humidifier, Durable For Extensive Supplemental Humidification During Ippb Treatments Or Oxygen Delivery
E0575	Nebulizer, Ultrasonic, Large Volume
E0600	Respiratory Suction Pump, Home Model, Portable Or Stationary, Electric
E0601	Continuous Positive Airway Pressure (Cpap) Device
E0617	External Defibrillator With Integrated Electrocardiogram Analysis
E0620	Skin Piercing Device For Collection Of Capillary Blood, Laser, Each
E0630	Patient Lift, Hydraulic Or Mechanical, Includes Any Seat, Sling, Strap(s) Or Pad(s)
E0635	Patient Lift, Electric With Seat Or Sling
E0636	Multipositional Patient Support System, With Integrated Lift, Patient Accessible Controls
E0639	Patient Lift, Moveable From Room To Room With Disassembly And Reassembly, Includes All Components/Accessories
E0640	Patient Lift, Fixed System, Includes All Components/Accessories
E0747	Osteogenesis Stimulator, Electrical, Non-Invasive, Other Than Spinal Applications
E0748	Osteogenesis Stimulator, Electrical, Non-Invasive, Spinal Applications
E0760	Ostogenesis Stimulator, Low Intensity Ultrasound, Non-Invasive
E0781	Ambulatory Infusion Pump, Single Or Multiple Channels, Electric Or Battery Operated, With Administrative Equipment, Worn By Patient
E0784	External Ambulatory Infusion Pump, Insulin
E0791	Parenteral Infusion Pump, Stationary, Single Or Multi-Channel
E0912	Trapeze Bar, Heavy Duty, For Patient Weight Capacity Greater Than 250 Pounds, Free Standing, Complete With Grab Bar
E0983	Manual Wheelchair Accessory, Power Add-On To Convert Manual Wheelchair To Motorized Wheelchair, Joystick Control
E0986	Manual Wheelchair Accessory, Push-Rim Activated Power Assist System
E0988	Manual Wheelchair Accessory, Lever-Activated, Wheel Drive, Pair
E1002	Wheelchair Accessory, Power Seating System, Tilt Only
E1003	Wheelchair Accessory, Power Seating System, Recline Only, Without Shear Reduction

HCPCS	Long Description
E1004	Wheelchair Accessory, Power Seating System, Recline Only, With Mechanical Shear Reduction
E1005	Wheelchair Accessory, Power Seating System, Recline Only, With Power Shear Reduction
E1006	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, Without Shear Reduction
E1007	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, With Mechanical Shear Reduction
E1008	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, With Power Shear Reduction
E1010	Wheelchair Accessory, Addition To Power Seating System, Power Leg Elevation System, Including Leg Rest, Pair
E1012	Wheelchair Accessory, Addition To Power Seating System, Center Mount Power Elevating Leg Rest/Platform, Complete System, Any Type, Each
E1030	Wheelchair Accessory, Ventilator Tray, Gimbaled
E1035	Multi-Positional Patient Transfer System, With Integrated Seat, Operated By Care Giver, Patient Weight Capacity Up To And Including 300 Pounds
E1036	Multi-Positional Patient Transfer System, Extra-Wide, With Integrated Seat, Operated By Caregiver, Patient Weight Capacity Greater Than 300 Pounds
E1037	Transport Chair, Pediatric Size
E1161	Manual Adult Size Wheelchair, Includes Tilt In Space
E1232	Wheelchair, Pediatric Size, Tilt-In-Space, Folding, Adjustable, With Seating System
E1233	Wheelchair, Pediatric Size, Tilt-In-Space, Rigid, Adjustable, Without Seating System
E1234	Wheelchair, Pediatric Size, Tilt-In-Space, Folding, Adjustable, Without Seating System
E1235	Wheelchair, Pediatric Size, Rigid, Adjustable, With Seating System
E1236	Wheelchair, Pediatric Size, Folding, Adjustable, With Seating System
E1237	Wheelchair, Pediatric Size, Rigid, Adjustable, Without Seating System
E1238	Wheelchair, Pediatric Size, Folding, Adjustable, Without Seating System
E1390	Oxygen Concentrator, Single Delivery Port, Capable Of Delivering 85 Percent Or Greater Oxygen Concentration At The Prescribed Flow Rate
E1391	Oxygen Concentrator, Dual Delivery Port, Capable Of Delivering 85 Percent Or Greater Oxygen Concentration At The Prescribed Flow Rate, Each
E1392	Portable Oxygen Concentrator, Rental
E1405	Oxygen And Water Vapor Enriching System With Heated Delivery
E1406	Oxygen And Water Vapor Enriching System Without Heated Delivery
E2000	Gastric Suction Pump, Home Model, Portable Or Stationary, Electric

HCPCS	Long Description
E2100	Blood Glucose Monitor With Integrated Voice Synthesizer
E2204	Manual Wheelchair Accessory, Nonstandard Seat Frame Depth, 22 To 25 Inches
E2227	Manual Wheelchair Accessory, Gear Reduction Drive Wheel, Each
E2228	Manual Wheelchair Accessory, Wheel Braking System And Lock, Complete, Each
E2310	Power Wheelchair Accessory, Electronic Connection Between Wheelchair Controller And One Power Seating System Motor, Including All Related Electronics, Indicator Feature, Mechanical Function Selection Switch, And Fixed Mounting Hardware
E2311	Power Wheelchair Accessory, Electronic Connection Between Wheelchair Controller And Two Or More Power Seating System Motors, Including All Related Electronics, Indicator Feature, Mechanical Function Selection Switch, And Fixed Mounting Hardware
E2312	Power Wheelchair Accessory, Hand Or Chin Control Interface, Mini-Proportional Remote Joystick, Proportional, Including Fixed Mounting Hardware
E2321	Power Wheelchair Accessory, Hand Control Interface, Remote Joystick, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Fixed Mounting Hardware
E2322	Power Wheelchair Accessory, Hand Control Interface, Multiple Mechanical Switches, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Fixed Mounting Hardware
E2325	Power Wheelchair Accessory, Sip And Puff Interface, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Manual Swingaway Mounting Hardware
E2327	Power Wheelchair Accessory, Head Control Interface, Mechanical, Proportional, Including All Related Electronics, Mechanical Direction Change Switch, And Fixed Mounting Hardware
E2328	Power Wheelchair Accessory, Head Control Or Extremity Control Interface, Electronic, Proportional, Including All Related Electronics And Fixed Mounting Hardware
E2329	Power Wheelchair Accessory, Head Control Interface, Contact Switch Mechanism, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, Mechanical Direction Change Switch, Head Array, And Fixed Mounting Hardware
E2330	Power Wheelchair Accessory, Head Control Interface, Proximity Switch Mechanism, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, Mechanical Direction Change Switch, Head Array, And Fixed Mounting Hardware
E2351	Power Wheelchair Accessory, Electronic Interface To Operate Speech Generating Device Using Power Wheelchair Control Interface
E2368	Power Wheelchair Component, Drive Wheel Motor, Replacement Only
E2369	Power Wheelchair Component, Drive Wheel Gear Box, Replacement

HCPCS	Long Description
	Only
E2370	Power Wheelchair Component, Integrated Drive Wheel Motor And Gear Box Combination, Replacement Only
E2373	Power Wheelchair Accessory, Hand Or Chin Control Interface, Compact Remote Joystick, Proportional, Including Fixed Mounting Hardware
E2374	Power Wheelchair Accessory, Hand Or Chin Control Interface, Standard Remote Joystick (Not Including Controller), Proportional, Including All Related Electronics And Fixed Mounting Hardware, Replacement Only
E2375	Power Wheelchair Accessory, Non-Expandable Controller, Including All Related Electronics And Mounting Hardware, Replacement Only
E2376	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics And Mounting Hardware, Replacement Only
E2377	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics And Mounting Hardware, Upgrade Provided At Initial Issue
E2378	Power Wheelchair Component, Actuator, Replacement Only
E2402	Negative Pressure Wound Therapy Electrical Pump, Stationary Or Portable
E2614	Positioning Wheelchair Back Cushion, Posterior, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware
E2616	Positioning Wheelchair Back Cushion, Posterior-Lateral, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware
E2620	Positioning Wheelchair Back Cushion, Planar Back With Lateral Supports, Width Less Than 22 Inches, Any Height, Including Any Type Mounting Hardware
E2621	Positioning Wheelchair Back Cushion, Planar Back With Lateral Supports, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware
E2626	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Adjustable
E2627	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Adjustable Rancho Type
E2628	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Reclining
E2629	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Friction Arm Support (Friction Dampening To Proximal And Distal Joints)
E2630	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support, Monosuspension Arm And Hand Support, Overhead Elbow Forearm Hand Sling Support, Yoke Type Suspension Support
K0002	Standard Hemi (Low Seat) Wheelchair
K0003	Lightweight Wheelchair
K0004	High Strength, Lightweight Wheelchair

HCPCS	Long Description
K0005	Ultralightweight Wheelchair
K0006	Heavy Duty Wheelchair
K0007	Extra Heavy Duty Wheelchair
K0009	Other Manual Wheelchair/Base
K0455	Infusion Pump Used For Uninterrupted Parenteral Administration Of Medication, (For example, Epoprostenol Or Treprostinol)
K0606	Automatic External Defibrillator, With Integrated Electrocardiogram Analysis, Garment Type
K0609	Replacement Electrodes For Use With Automated External Defibrillator, Garment Type Only, Each
K0730	Controlled Dose Inhalation Drug Delivery System
K0738	Portable Gaseous Oxygen System, Rental; Home Compressor Used To Fill Portable Oxygen Cylinders; Includes Portable Containers, Regulator, Flowmeter, Humidifier, Cannula Or Mask, And Tubing
K0800	Power Operated Vehicle, Group 1 Standard, Patient Weight Capacity Up To And Including 300 Pounds
K0801	Power Operated Vehicle, Group 1 Heavy Duty, Patient Weight Capacity, 301 To 450 Pounds
K0802	Power Operated Vehicle, Group 1 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds
K0806	Power Operated Vehicle, Group 2 Standard, Patient Weight Capacity Up To And Including 300 Pounds
K0807	Power Operated Vehicle, Group 2 Heavy Duty, Patient Weight Capacity 301 To 450 Pounds
K0808	Power Operated Vehicle, Group 2 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds
K0813	Power Wheelchair, Group 1 Standard, Portable, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds
K0814	Power Wheelchair, Group 1 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0815	Power Wheelchair, Group 1 Standard, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds
K0816	Power Wheelchair, Group 1 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0820	Power Wheelchair, Group 2 Standard, Portable, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0821	Power Wheelchair, Group 2 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0822	Power Wheelchair, Group 2 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0823	Power Wheelchair, Group 2 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0824	Power Wheelchair, Group 2 Heavy Duty, Sling/Solid Seat/Back, Patient

HCPCS	Long Description
	Weight Capacity 301 To 450 Pounds
K0825	Power Wheelchair, Group 2 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0826	Power Wheelchair, Group 2 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0827	Power Wheelchair, Group 2 Very Heavy Duty, Captains Chair, Patient Weight Capacity 451 To 600 Pounds
K0828	Power Wheelchair, Group 2 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
K0829	Power Wheelchair, Group 2 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More
K0835	Power Wheelchair, Group 2 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0836	Power Wheelchair, Group 2 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0837	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0838	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0839	Power Wheelchair, Group 2 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0840	Power Wheelchair, Group 2 Extra Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
K0841	Power Wheelchair, Group 2 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0842	Power Wheelchair, Group 2 Standard, Multiple Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0843	Power Wheelchair, Group 2 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0848	Power Wheelchair, Group 3 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0849	Power Wheelchair, Group 3 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0850	Power Wheelchair, Group 3 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0851	Power Wheelchair, Group 3 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0852	Power Wheelchair, Group 3 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0853	Power Wheelchair, Group 3 Very Heavy Duty, Captains Chair, Patient Weight Capacity, 451 To 600 Pounds
K0854	Power Wheelchair, Group 3 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More

HCPCS	Long Description
K0855	Power Wheelchair, Group 3 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More
K0856	Power Wheelchair, Group 3 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0857	Power Wheelchair, Group 3 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0858	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0859	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0860	Power Wheelchair, Group 3 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0861	Power Wheelchair, Group 3 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0862	Power Wheelchair, Group 3 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0863	Power Wheelchair, Group 3 Very Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0864	Power Wheelchair, Group 3 Extra Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
L0631	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L0635	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panel(S), Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment
L0636	Lumbar Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Custom Fabricated

HCPCS	Long Description
L0637	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L0638	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated
L0639	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L0640	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Custom Fabricated
L0648	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf
L0650	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf

HCPCS	Long Description
L0651	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf
L1680	Hip Orthosis, Abduction Control Of Hip Joints, Dynamic, Pelvic Control, Adjustable Hip Motion Control, Thigh Cuffs (Rancho Hip Action Type), Custom Fabricated
L1685	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Custom Fabricated
L1686	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting And Adjustment
L1690	Combination, Bilateral, Lumbo-Sacral, Hip, Femur Orthosis Providing Adduction And Internal Rotation Control, Prefabricated, Includes Fitting And Adjustment
L1700	Legg Perthes Orthosis, (Toronto Type), Custom-Fabricated
L1710	Legg Perthes Orthosis, (Newington Type), Custom Fabricated
L1720	Legg Perthes Orthosis, Trilateral, (Tachdijan Type), Custom-Fabricated
L1730	Legg Perthes Orthosis, (Scottish Rite Type), Custom-Fabricated
L1755	Legg Perthes Orthosis, (Patten Bottom Type), Custom-Fabricated
L1832	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1833	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The Shelf
L1834	Knee Orthosis, Without Knee Joint, Rigid, Custom-Fabricated
L1840	Knee Orthosis, Derotation, Medial-Lateral, Anterior Cruciate Ligament, Custom Fabricated
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated

HCPCS	Long Description
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated
L1847	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1848	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated, Off-The-Shelf
L1851	Knee Orthosis (Ko), Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf
L1852	Knee Orthosis (Ko), Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf
L1860	Knee Orthosis, Modification Of Supracondylar Prosthetic Socket, Custom-Fabricated (Sk)
L1907	Ankle Orthosis, Supramalleolar With Straps, With Or Without Interface/Pads, Custom Fabricated
L1932	Afo, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated
L1945	Ankle Foot Orthosis, Plastic, Rigid Anterior Tibial Section (Floor Reaction), Custom-Fabricated
L1950	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic, Custom-Fabricated
L1951	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated
L2000	Knee Ankle Foot Orthosis, Single Upright, Free Knee, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar Ak Orthosis), Custom-

HCPCS	Long Description
	Fabricated
L2005	Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Any Type Activation, Includes Ankle Joint, Any Type, Custom Fabricated
L2010	Knee Ankle Foot Orthosis, Single Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar Ak Orthosis), Without Knee Joint, Custom-Fabricated
L2020	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Double Bar Ak Orthosis), Custom-Fabricated
L2030	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs, (Double Bar Ak Orthosis), Without Knee Joint, Custom Fabricated
L2034	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, With Or Without Free Motion Knee, Medial Lateral Rotation Control, With Or Without Free Motion Ankle, Custom Fabricated
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated
L2037	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated
L2038	Knee Ankle Foot Orthosis, Full Plastic, With Or Without Free Motion Knee, Multi-Axis Ankle, Custom Fabricated
L2050	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Hip Joint, Pelvic Band/Belt, Custom-Fabricated
L2060	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Ball Bearing Hip Joint, Pelvic Band/ Belt, Custom-Fabricated
L2106	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated
L2108	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Custom-Fabricated
L2114	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment
L2116	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment
L2126	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated
L2128	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Custom-Fabricated
L2132	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment
L2134	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Semi-Rigid,

HCPCS	Long Description
	Prefabricated, Includes Fitting And Adjustment
L2136	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment
L2350	Addition To Lower Extremity, Prosthetic Type, (Bk) Socket, Molded To Patient Model, (Used For Ptb Afo Orthoses)
L2510	Addition To Lower Extremity, Thigh/Weight Bearing, Quadri- Lateral Brim, Molded To Patient Model
L2525	Addition To Lower Extremity, Thigh/Weight Bearing, Ischial Containment/Narrow M-L Brim Molded To Patient Model
L2526	Addition To Lower Extremity, Thigh/Weight Bearing, Ischial Containment/Narrow M-L Brim, Custom Fitted
L2570	Addition To Lower Extremity, Pelvic Control, Hip Joint, Clevis Type Two Position Joint, Each
L2627	Addition To Lower Extremity, Pelvic Control, Plastic, Molded To Patient Model, Reciprocating Hip Joint And Cables
L2628	Addition To Lower Extremity, Pelvic Control, Metal Frame, Reciprocating Hip Joint And Cables
L3330	Lift, Elevation, Metal Extension (Skate)
L3671	Shoulder Orthosis, Shoulder Joint Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3674	Shoulder Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, With Or Without Nontorsion Joint/Turnbuckle, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3720	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Free Motion, Custom-Fabricated
L3730	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Extension/ Flexion Assist, Custom-Fabricated
L3740	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Adjustable Position Lock With Active Control, Custom-Fabricated
L3761	Elbow Orthosis (Eo), With Adjustable Position Locking Joint(S), Prefabricated, Off-The-Shelf
L3763	Elbow Wrist Hand Orthosis, Rigid, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3764	Elbow Wrist Hand Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3765	Elbow Wrist Hand Finger Orthosis, Rigid, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment

HCPCS	Long Description
L3766	Elbow Wrist Hand Finger Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3900	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Wrist Or Finger Driven, Custom-Fabricated
L3901	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Cable Driven, Custom-Fabricated
L3904	Wrist Hand Finger Orthosis, External Powered, Electric, Custom-Fabricated
L3905	Wrist Hand Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3960	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment
L3961	Shoulder Elbow Wrist Hand Orthosis, Shoulder Cap Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3962	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Erbs Palsey Design, Prefabricated, Includes Fitting And Adjustment
L3967	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3971	Shoulder Elbow Wrist Hand Orthosis, Shoulder Cap Design, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3973	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3975	Shoulder Elbow Wrist Hand Finger Orthosis, Shoulder Cap Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3976	Shoulder Elbow Wrist Hand Finger Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3977	Shoulder Elbow Wrist Hand Finger Orthosis, Shoulder Cap Design, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment

HCPCS	Long Description
L3978	Shoulder Elbow Wrist Hand Finger Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3981	Upper Extremity Fracture Orthosis, Humeral, Prefabricated, Includes Shoulder Cap Design, With Or Without Joints, Forearm Section, May Include Soft Interface, Straps, Includes Fitting And Adjustments
L4010	Replace Trilateral Socket Brim
L4020	Replace Quadrilateral Socket Brim, Molded To Patient Model
L4030	Replace Quadrilateral Socket Brim, Custom Fitted
L4130	Replace Pretibial Shell
L4631	Ankle Foot Orthosis, Walking Boot Type, Varus/Valgus Correction, Rocker Bottom, Anterior Tibial Shell, Soft Interface, Custom Arch Support, Plastic Or Other Material, Includes Straps And Closures, Custom Fabricated
L5000	Partial Foot, Shoe Insert With Longitudinal Arch, Toe Filler
L5010	Partial Foot, Molded Socket, Ankle Height, With Toe Filler
L5020	Partial Foot, Molded Socket, Tibial Tubercle Height, With Toe Filler
L5050	Ankle, Symes, Molded Socket, Sach Foot
L5060	Ankle, Symes, Metal Frame, Molded Leather Socket, Articulated Ankle/Foot
L5100	Below Knee, Molded Socket, Shin, Sach Foot
L5105	Below Knee, Plastic Socket, Joints And Thigh Lacer, Sach Foot
L5150	Knee Disarticulation (Or Through Knee), Molded Socket, External Knee Joints, Shin, Sach Foot
L5160	Knee Disarticulation (Or Through Knee), Molded Socket, Bent Knee Configuration, External Knee Joints, Shin, Sach Foot
L5200	Above Knee, Molded Socket, Single Axis Constant Friction Knee, Shin, Sach Foot
L5210	Above Knee, Short Prosthesis, No Knee Joint (Stubbies), With Foot Blocks, No Ankle Joints, Each
L5220	Above Knee, Short Prosthesis, No Knee Joint (Stubbies), With Articulated Ankle/Foot, Dynamically Aligned, Each
L5230	Above Knee, For Proximal Femoral Focal Deficiency, Constant Friction Knee, Shin, Sach Foot
L5250	Hip Disarticulation, Canadian Type; Molded Socket, Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot
L5270	Hip Disarticulation, Tilt Table Type; Molded Socket, Locking Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot
L5280	Hemipelvectomy, Canadian Type; Molded Socket, Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot
L5301	Below Knee, Molded Socket, Shin, Sach Foot, Endoskeletal System

HCPCS	Long Description
L5312	Knee Disarticulation (Or Through Knee), Molded Socket, Single Axis Knee, Pylon, Sach Foot, Endoskeletal System
L5321	Above Knee, Molded Socket, Open End, Sach Foot, Endoskeletal System, Single Axis Knee
L5331	Hip Disarticulation, Canadian Type, Molded Socket, Endoskeletal System, Hip Joint, Single Axis Knee, Sach Foot
L5341	Hemipelvectomy, Canadian Type, Molded Socket, Endoskeletal System, Hip Joint, Single Axis Knee, Sach Foot
L5400	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment, Suspension, And One Cast Change, Below Knee
L5420	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment And Suspension And One Cast Change Ak Or Knee Disarticulation
L5430	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Incl. Fitting, Alignment And Suspension, Ak Or Knee Disarticulation, Each Additional Cast Change And Realignment
L5460	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Above Knee
L5500	Initial, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5505	Initial, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5510	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5520	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5530	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5535	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, No Cover, Sach Foot, Prefabricated, Adjustable Open End Socket
L5540	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Model
L5560	Preparatory, Above Knee- Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5570	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5580	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5585	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket,

HCPCS	Long Description
	Non-Alignable System, Pylon, No Cover, Sach Foot, Prefabricated Adjustable Open End Socket
L5590	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon No Cover, Sach Foot, Laminated Socket, Molded To Model
L5595	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Patient Model
L5600	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Patient Model
L5610	Addition To Lower Extremity, Endoskeletal System, Above Knee, Hydracadence System
L5611	Addition To Lower Extremity, Endoskeletal System, Above Knee - Knee Disarticulation, 4 Bar Linkage, With Friction Swing Phase Control
L5613	Addition To Lower Extremity, Endoskeletal System, Above Knee-Knee Disarticulation, 4 Bar Linkage, With Hydraulic Swing Phase Control
L5614	Addition To Lower Extremity, Exoskeletal System, Above Knee-Knee Disarticulation, 4 Bar Linkage, With Pneumatic Swing Phase Control
L5616	Addition To Lower Extremity, Endoskeletal System, Above Knee, Universal Multiplex System, Friction Swing Phase Control
L5617	Addition To Lower Extremity, Quick Change Self-Aligning Unit, Above Knee Or Below Knee, Each
L5626	Addition To Lower Extremity, Test Socket, Hip Disarticulation
L5628	Addition To Lower Extremity, Test Socket, Hemipelvectomy
L5638	Addition To Lower Extremity, Below Knee, Leather Socket
L5639	Addition To Lower Extremity, Below Knee, Wood Socket
L5640	Addition To Lower Extremity, Knee Disarticulation, Leather Socket
L5642	Addition To Lower Extremity, Above Knee, Leather Socket
L5643	Addition To Lower Extremity, Hip Disarticulation, Flexible Inner Socket, External Frame
L5644	Addition To Lower Extremity, Above Knee, Wood Socket
L5645	Addition To Lower Extremity, Below Knee, Flexible Inner Socket, External Frame
L5646	Addition To Lower Extremity, Below Knee, Air, Fluid, Gel Or Equal, Cushion Socket
L5647	Addition To Lower Extremity, Below Knee Suction Socket
L5648	Addition To Lower Extremity, Above Knee, Air, Fluid, Gel Or Equal, Cushion Socket
L5649	Addition To Lower Extremity, Ischial Containment/Narrow M-L Socket
L5650	Additions To Lower Extremity, Total Contact, Above Knee Or Knee Disarticulation Socket
L5651	Addition To Lower Extremity, Above Knee, Flexible Inner Socket, External Frame
L5653	Addition To Lower Extremity, Knee Disarticulation, Expandable Wall Socket

HCPCS	Long Description
L5661	Addition To Lower Extremity, Socket Insert, Multi-Durometer Symes
L5665	Addition To Lower Extremity, Socket Insert, Multi-Durometer, Below Knee
L5671	Addition To Lower Extremity, Below Knee / Above Knee Suspension Locking Mechanism (Shuttle, Lanyard Or Equal), Excludes Socket Insert
L5673	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric Or Equal, For Use With Locking Mechanism
L5677	Additions To Lower Extremity, Below Knee, Knee Joints, Polycentric, Pair
L5679	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric Or Equal, Not For Use With Locking Mechanism
L5681	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated Socket Insert For Congenital Or Atypical Traumatic Amputee, Silicone Gel, Elastomeric Or Equal, For Use With Or Without Locking Mechanism, Initial Only (For Other Than Initial, Use Code L5673 Or L5679)
L5682	Addition To Lower Extremity, Below Knee, Thigh Lacer, Gluteal/Ischial, Molded
L5683	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated Socket Insert For Other Than Congenital Or Atypical Traumatic Amputee, Silicone Gel, Elastomeric Or Equal, For Use With Or Without Locking Mechanism, Initial Only (For Other Than Initial, Use Code L5673 Or L5679)
L5700	Replacement, Socket, Below Knee, Molded To Patient Model
L5701	Replacement, Socket, Above Knee/Knee Disarticulation, Including Attachment Plate, Molded To Patient Model
L5702	Replacement, Socket, Hip Disarticulation, Including Hip Joint, Molded To Patient Model
L5703	Ankle, Symes, Molded To Patient Model, Socket Without Solid Ankle Cushion Heel (Sach) Foot, Replacement Only
L5704	Custom Shaped Protective Cover, Below Knee
L5705	Custom Shaped Protective Cover, Above Knee
L5706	Custom Shaped Protective Cover, Knee Disarticulation
L5707	Custom Shaped Protective Cover, Hip Disarticulation
L5711	Additions Exoskeletal Knee-Shin System, Single Axis, Manual Lock, Ultra-Light Material
L5716	Addition, Exoskeletal Knee-Shin System, Polycentric, Mechanical Stance Phase Lock
L5718	Addition, Exoskeletal Knee-Shin System, Polycentric, Friction Swing And Stance Phase Control

HCPCS	Long Description
L5722	Addition, Exoskeletal Knee-Shin System, Single Axis, Pneumatic Swing, Friction Stance Phase Control
L5724	Addition, Exoskeletal Knee-Shin System, Single Axis, Fluid Swing Phase Control
L5726	Addition, Exoskeletal Knee-Shin System, Single Axis, External Joints Fluid Swing Phase Control
L5728	Addition, Exoskeletal Knee-Shin System, Single Axis, Fluid Swing And Stance Phase Control
L5780	Addition, Exoskeletal Knee-Shin System, Single Axis, Pneumatic/Hydra Pneumatic Swing Phase Control
L5781	Addition To Lower Limb Prosthesis, Vacuum Pump, Residual Limb Volume Management And Moisture Evacuation System
L5782	Addition To Lower Limb Prosthesis, Vacuum Pump, Residual Limb Volume Management And Moisture Evacuation System, Heavy Duty
L5785	Addition, Exoskeletal System, Below Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5790	Addition, Exoskeletal System, Above Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5795	Addition, Exoskeletal System, Hip Disarticulation, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5810	Addition, Endoskeletal Knee-Shin System, Single Axis, Manual Lock
L5811	Addition, Endoskeletal Knee-Shin System, Single Axis, Manual Lock, Ultra-Light Material
L5812	Addition, Endoskeletal Knee-Shin System, Single Axis, Friction Swing And Stance Phase Control (Safety Knee)
L5814	Addition, Endoskeletal Knee-Shin System, Polycentric, Hydraulic Swing Phase Control, Mechanical Stance Phase Lock
L5816	Addition, Endoskeletal Knee-Shin System, Polycentric, Mechanical Stance Phase Lock
L5818	Addition, Endoskeletal Knee-Shin System, Polycentric, Friction Swing, And Stance Phase Control
L5822	Addition, Endoskeletal Knee-Shin System, Single Axis, Pneumatic Swing, Friction Stance Phase Control
L5824	Addition, Endoskeletal Knee-Shin System, Single Axis, Fluid Swing Phase Control
L5826	Addition, Endoskeletal Knee-Shin System, Single Axis, Hydraulic Swing Phase Control, With Miniature High Activity Frame
L5828	Addition, Endoskeletal Knee-Shin System, Single Axis, Fluid Swing And Stance Phase Control
L5830	Addition, Endoskeletal Knee-Shin System, Single Axis, Pneumatic/ Swing Phase Control
L5840	Addition, Endoskeletal Knee/Shin System, 4-Bar Linkage Or Multiaxial, Pneumatic Swing Phase Control

HCPCS	Long Description
L5845	Addition, Endoskeletal, Knee-Shin System, Stance Flexion Feature, Adjustable
L5848	Addition To Endoskeletal Knee-Shin System, Fluid Stance Extension, Dampening Feature, With Or Without Adjustability
L5856	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Microprocessor Control Feature, Swing And Stance Phase, Includes Electronic Sensor(S), Any Type
L5857	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Microprocessor Control Feature, Swing Phase Only, Includes Electronic Sensor(S), Any Type
L5858	Addition To Lower Extremity Prosthesis, Endoskeletal Knee Shin System, Microprocessor Control Feature, Stance Phase Only, Includes Electronic Sensor(S), Any Type
L5859	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Powered And Programmable Flexion/Extension Assist Control, Includes Any Type Motor(S)
L5920	Addition, Endoskeletal System, Above Knee Or Hip Disarticulation, Alignable System
L5930	Addition, Endoskeletal System, High Activity Knee Control Frame
L5940	Addition, Endoskeletal System, Below Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5950	Addition, Endoskeletal System, Above Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5960	Addition, Endoskeletal System, Hip Disarticulation, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5961	Addition, Endoskeletal System, Polycentric Hip Joint, Pneumatic Or Hydraulic Control, Rotation Control, With Or Without Flexion And/Or Extension Control
L5962	Addition, Endoskeletal System, Below Knee, Flexible Protective Outer Surface Covering System
L5964	Addition, Endoskeletal System, Above Knee, Flexible Protective Outer Surface Covering System
L5966	Addition, Endoskeletal System, Hip Disarticulation, Flexible Protective Outer Surface Covering System
L5968	Addition To Lower Limb Prosthesis, Multiaxial Ankle With Swing Phase Active Dorsiflexion Feature
L5973	Endoskeletal Ankle Foot System, Microprocessor Controlled Feature, Dorsiflexion And/Or Plantar Flexion Control, Includes Power Source
L5976	All Lower Extremity Prostheses, Energy Storing Foot (Seattle Carbon Copy Ii Or Equal)
L5979	All Lower Extremity Prosthesis, Multi-Axial Ankle, Dynamic Response Foot, One Piece System
L5980	All Lower Extremity Prostheses, Flex Foot System
L5981	All Lower Extremity Prostheses, Flex-Walk System Or Equal

HCPCS	Long Description
L5982	All Exoskeletal Lower Extremity Prostheses, Axial Rotation Unit
L5984	All Endoskeletal Lower Extremity Prosthesis, Axial Rotation Unit, With Or Without Adjustability
L5986	All Lower Extremity Prostheses, Multi-Axial Rotation Unit (Mcp Or Equal)
L5987	All Lower Extremity Prosthesis, Shank Foot System With Vertical Loading Pylon
L5988	Addition To Lower Limb Prosthesis, Vertical Shock Reducing Pylon Feature
L5990	Addition To Lower Extremity Prosthesis, User Adjustable Heel Height
L8035	Custom Breast Prosthesis, Post Mastectomy, Molded To Patient Model
V2531	Contact Lens, Scleral, Gas Permeable, Per Lens (For Contact Lens Modification, See 92325)

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VII. DMEPOS Competitive Bidding Program (CBP) Amendments

A. Background

Medicare pays for certain DMEPOS items and services furnished within competitive bidding areas based on the payment rules that are set forth in section 1847 of the Social Security Act (the Act) and 42 CFR part 414, subpart F. We proposed to revise the existing DMEPOS Competitive Bidding Program (CBP) change of ownership (CHOW) regulations in § 414.422(d) in recognition of the fact that CHOWs may occur on shorter timeframes than our regulations previously contemplated. We also proposed to revise § 414.423(f) for the submission of a hearing request in notices of breach of contract.

B. Proposed Amendments

We proposed to revise the following amendments in § 414.422(d) as follows:

- We proposed to add the acronym ''CHOW'' after the title of the paragraph and use the acronym throughout the section where we previously wrote out in full text ''change of ownership''.
- We proposed to remove the notification requirement at paragraph (d)(1) because we no longer believe it is necessary for CMS to be notified 60 days in advance when a contract supplier is negotiating a CHOW. In past rounds of the CBP, there have been situations in which contract suppliers have undergone CHOWs within the 60-day timeframe and they were unable to meet the 60-day notice requirement due to circumstances that were not fully within their control. We recognize that the 60-day notice requirement is a bit onerous and as such we proposed to remove paragraph (d)(1) in its entirety. We also proposed to redesignate and reorganize the remaining text of paragraph (d).
- We proposed to remove the distinction of a ''new entity'' from paragraph (d)(2)(ii) in its entirety, and retain the successor entity requirements in paragraph (d)(2)(i) with changes, as we are aligning the CHOW requirements for all entities, regardless of whether a ''new'' entity is formed as a result of the CHOW. We also proposed to revise the requirement to submit the documentation described in § 414.414(b) through (d) from 30 days prior to the anticipated effective date of the CHOW to instead require submission prior to the effective date of the CHOW. We further proposed to change the requirement on submission of a signed novation agreement 30 days before the CHOW to instead require that the novation agreement be submitted by the successor entity no later than 10 days after the effective date of the CHOW. We want to allow flexibility for the timing of submission of documents since it may not always be possible for the successor entity to submit the applicable documentation 30 days before the anticipated effective date of the CHOW. Through our education and outreach efforts, we will encourage the successor entity to work with CMS to submit draft documentation as far in advance as possible for CMS to review to ensure that the novation agreement is acceptable to CMS. We believe shortening the timeframe for submission from 30 days to 10 days will expedite CMS's determination on whether to allow transfer of the contract to the successor entity. We also proposed that the successor entity must submit a novation agreement that states that it assumes all obligations under the contract.
- We proposed to remove the phrase ''new qualified'' before ''entity'' and replace it with the term ''successor'' in paragraph (d)(3) as this is applicable to all successor entities. We also proposed to add the term ''may'' to make it clear that the transfer of the entire contract to a successor entity is at CMS' discretion upon CMS' review of all required documentation. The revision will align with existing language in paragraph (d)(4), which specifies that CMS may transfer the portion of the contract if certain conditions are met.
- We proposed to revise paragraph (d)(4) by removing the ''*e.g.*'' parenthetical after ''distinct company'' to retain only the example of a subsidiary, and noting it as ''for example'' as we realized that it is the clearest example. In addition, some of the other examples were not accurate (for example, a sole proprietor) and this could lead to confusion. We also proposed to remove the reference to ''new qualified'' before ''entity'' and replace it with the term ''successor,'' as the resulting entity in a transfer of a portion of the contract may not result in a ''new'' entity but will always result in a ''successor'' entity. In addition, we proposed to remove the phrase ''new qualified owner who'' in paragraph (d)(4)(i) and replace it with ''successor entity that'' to align with the language used throughout § 414.422(d). We also proposed to remove the acronym ''*i.e.*'' and replace it with ''that is.''

In § 414.423(f)(2), we require that a request for a hearing be ''received by'' the Competitive Bidding Implementation Contractor (CBIC) within 30 days from the date of the notice of breach of contract. We proposed to revise paragraph (f)(2) to specify that the request for a hearing

must be ''submitted to'' the CBIC rather than ''received by'' the CBIC within 30 days from the date of the notice of breach of contract. Previously, the CBIC was only able to receive a written request via mail or fax for a hearing from a contract supplier, however, now contract suppliers have a secure online method to submit hearing requests. Now that hearing requests can be submitted online, it will be apparent to all parties when the request for a hearing is submitted, as the date on which the request was received by the CBIC was not apparent to suppliers in the past. Furthermore, this revision aligns with language used throughout § 414.423.

We solicited public comments on these amendments. We received comments in support of our CHOW proposal to remove the 60-day requirement and require submission of the novation agreement within 10 days of the effective date of the CHOW. We did not receive any comments on our other proposals for CHOWs or on our proposal for submission of a hearing request in a notice of a breach of contract appeal. We are finalizing our DMEPOS CBP proposals without change.

VIII. Requests for Information

A. Data Collection

1. Technical Expert Panel on Improving the Reporting of Composite Rate Costs Under the ESRD PPS

a. Background

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), a Technical Expert Panel (TEP) was held on December 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. CMS contracted with a data contractor to convene this TEP and conduct research and analysis to refine the case-mix adjustment model. This TEP represented the first step in acquiring stakeholder and expert input to inform these refinements. The final TEP report and other materials can be found at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html.*

The TEP was comprised of 16 expert stakeholders, including ESRD facilities, representatives of professional associations, independent academic clinical researchers, and patient advocates. In addition, a select number of observers attended, including representatives of governmental agencies and independent policy advisory groups. The TEP was organized into seven sessions, including an overview of the ESRD PPS and the cost components of dialysis treatment, four topical sessions corresponding to potential data collection strategies, and a final summary session.

b. Summary of the Data Contractor's Presentation to the TEP

i. Components of Dialysis Treatment Costs and Limitations of Current Data Collection

The data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. Nevertheless, under current reporting practices, there are no data on the patient- and treatment-level variation in the cost of composite rate items and services. These findings underscore the importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

ii. Data Collection Options

The data contractor presented the participants in the TEP with several options for optimizing data collection on composite rate items and services, and each option was specifically formulated to minimize reporting burden for ESRD facilities where possible. Feedback on these options and input on alternative approaches, as provided by the participants, would be used to further develop practical approaches for more accurate data collection.

Among the options presented for optimizing the collection of composite rate cost data were (1) improving the accuracy of charges and/or itemizing the use of composite rate services on claims; (2) reporting duration of each dialysis treatment session on claims (3) identifying and allocating costs to discrete categories of patients or patient characteristics that are associated with high cost of treatment; and (4) improving the reporting of facility-level costs. Each of these options is described in the following sections. The TEP participants' responses to these approaches are summarized in the Key Findings section at the end of this section. We note that our summary of the key findings is based on a review of the individual comments and is not meant to represent a consensus view shared by all TEP participants, but rather to consolidate related suggestions made by one or more participant.

iii. Improving the Accuracy of Charges

The data contractor presented two approaches for directly collecting data on the utilization of composite rate items and services. The first was to require more accurate reporting of charges for each dialysis session. Recent analysis of charge data revealed little variation in charges for any given revenue center code associated with a dialysis treatment, indicating that facilities are using standardized charges. The second approach was to require itemized reporting of all or a limited number of high cost composite rate items and services. Beginning in 2015,[44] ESRD facilities were required to report selected composite rate services that were included on the Consolidated Billing List (CBL), however, the data contractor's analysis of reporting on use of these items showed that compliance has been minimal. Participants noted that these two options would be burdensome for ESRD facilities.

iv. Collection of Data on Duration of Dialysis Treatment

A singular option that would provide sufficient data to develop a refined case-mix adjustment model is the collection of dialysis treatment duration for each session. If dialysis session time were reported for each dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in composite rate costs could be attributed to two discrete categories: Differences due to dialysis treatment duration (measured in units of time) and differences unrelated to treatment duration. Treatment duration would not be used to directly adjust payment, rather, it would be used to apportion composite rate costs that are currently only observable at the facility level to the patient or treatment level for use in the case-mix adjustment. Data on the duration of dialysis session would allow for a proportionately higher proportion of composite rate costs to be allocated to patients with longer dialysis treatment times.

The data contractor provided examples of ways that longer duration of dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased

[44] Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978. December 2, 2014 (pp 3–4). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf.*

per-treatment capital costs. Additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and patients with increased use of dialysate and water treatment supplies or equipment likely have higher average per-treatment supply costs.

The data contractor proposed two approaches to collect treatment duration data: (1) Use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) on delivered dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN) or (2) have ESRD facilities report treatment duration on Medicare claims. For the latter, treatment duration data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each dialysis treatment or by updating the definition of the existing revenue center code for dialysis treatments so that the units correspond to treatment time instead of the number of treatments. ESRD facilities already report to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that facilities currently collect treatment duration.[45] Moreover, many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every dialysis treatment, minimizing additional burden of reporting this metric on claims.

v. Capturing Variation in Costs Associated With Complex Patients

Participants on the TEP also discussed the variation in composite rate costs that is independent of treatment duration and associated with severity of illness or disability in the dialysis patient population. In preparation for the TEP, the data contractor interviewed a number of ESRD facilities to identify sources of composite rate cost variation associated with the provision of care to more complex patients. Patient level-factors identified during the course of these interviews and during the TEP included seven points: (1) Maintenance of isolation rooms and use of dedicated nurses to attend patients with active hepatitis B infection; (2) treatment and care for incident dialysis patients (first 120 days); (3) treatment and care for catheterized patients; (4) pre- and post-dialysis session care for non-ambulatory patients; (5) treatment and care for pediatric patients; (6) treatment of patients exhibiting behavioral problems related to mental illness/drug dependency; and (7) treatment and care for home dialysis patients.

During the TEP, participants identified additional factors associated with higher treatment costs. These included hemodynamic instability, dual eligibility for Medicare and Medicaid, depression or mental illness, poor functional status, no primary caregiver, and institutionalized status or incarcerated or residence in a skilled nursing facility.

A common thread among these factors is that they all require more intense use of labor, especially direct patient care staff and highly specialized nursing or social work care or other intervention, such as would be provided by staff to assist in transfer for non-ambulatory patients.

The data contractor described alternative approaches for collecting sufficient data on these composite rate costs to inform a refined case-mix adjustment model. The first would entail reporting such items and services as line items on the claim. The second would involve grouping patients into a set of ''high-risk'' or ''high-cost'' patient types, in a hierarchical fashion and apportioning costs to each patient grouping based on known use of services.

vi. Facility-Level Costs

The TEP also included discussion of facility-level costs, identifying drivers of these costs, and the ESRD facility characteristics that may result in cost differences across facility types and potential revisions to the cost reports to better capture these costs. Participants on the TEP indicated that drivers of facility-level costs include: (1) Facility size (treatment volume and treatment capacity), which affects economies of scale; (2) geographic location, which affects both input prices and wages; (3) hospital versus freestanding status; (4) ownership type; and (5) whether the facility offers specialized services, such as pediatric or home dialysis treatment. These facility characteristics can affect both capital and labor costs, as well as the costs for drugs, laboratory tests and supplies.

c. Key Findings

Based on a review of the individual participant responses to each of the data collection options, CMS has summarized key conclusions in the following sections. The sections are arranged in the order of the topical sessions, as they were presented earlier.

i. Components of Dialysis Treatment Costs and Limitations of Current Data Collection

During this session, the participants agreed that capital, labor, and administrative costs make up the majority of composite rate costs. They stated that the level of complexity of dialysis patients has been increasing over time, and noted some costs at the margins (for example, information technology costs) that are not reflected in cost reports. Participants were averse to reporting individualized charges to reflect treatment-level variation in the items and services provided, unless this reporting was somehow linked to payment.

ii. Duration of Dialysis Treatment

To record time on dialysis, participants preferred that the data be collected on Medicare claims. They did not support using existing CROWNWeb data on treatment duration, as there were too many questions about its completeness and timeliness. They agreed that if duration of dialysis treatment time is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. The participants cautioned that reporting time on dialysis on the claims would place additional burden on facilities, but for facilities with EHRs, the burden associated with the collection of dialysis treatment time is expected to be small and temporary because the information is already collected. Collecting time on dialysis could be difficult to accomplish for ESRD facilities that do not use EHRs. Some participants maintained that certain factors related to patient complexity—such as comorbidities and mental health status—that are associated with treatment costs are unrelated to treatment duration.

iii. Identifying Costs Associated With Complex Patients

The participants expressed support for improving consistency in cost reporting across facilities. They recommended clarifying cost report instructions to ensure comparable reporting across facilities. They agreed that labor is the major source of patient-level cost variation, but expressed concern that allocating labor costs to the patient level or even the patient type would pose significant challenges. The participants noted that certain high-cost items and services used to treat complex patients, such as isolation rooms or lifts, could be easily itemized on claims and

[45] Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2021-Technical-Specifications-.pdf.*

reported in cost reports. They proposed alternative approaches for quantifying resource use associated with complex patients, such as classifying resource use by intensity of care provided or tracking staff time across patients.

iv. Facility-Level Costs

The participants stated that there are differences in cost at the facility level associated with the characteristics presented in the Facility-level Drivers of Cost session. They noted EHR practices are also associated with variation in facility-level cost. In addition, they emphasized that treatment volume relative to capacity has a significant financial impact on dialysis facilities; however, these costs currently are not reflected in cost reports. They also suggested that it might be beneficial to reflect missed treatments through a capacity utilization measure on the cost report and this could distinguish between more costly missed treatments and less costly planned absences, as the latter can be adjusted so that the facility chair is filled. The participants also indicated that rural facilities have costs not incurred by non-rural facilities, even among facilities with similar treatment volume, and do not believe the low volume payment adjustment and rural adjuster to be redundant.

d. Summary

This TEP focused on data collection on composite rate costs to inform the development of a more refined case-mix adjustment model for the ESRD PPS. Currently two equations are used to calculate the base rate for payment: (1) One at the facility level and, (2) one at the patient or treatment level—because items in the composite rate are not collected at the patient level.[46]

While formerly separately billable items and services are itemized at the treatment level on claims and also reflected in cost reports, composite rate services, which comprise the bulk of the total costs for dialysis treatment are not itemized and can only be estimated at the facility level from cost reports. Charges for these services, as reported on claims, show little variation across facilities and cannot be used for estimating patient- or treatment-level variation in cost. Solutions for optimizing data collection on individual use of composite rate services were proposed by the data contractor and discussed by the participants. CMS' current goal, as emphasized throughout the TEP, is to explore options to improve the identification of per-treatment composite rate costs, and we invite comment on all of the options proposed during this TEP and discussed as part of this comment solicitation. We agree with the participants on the TEP that the benefits of improving the ESRD PPS case-mix adjustment model must be weighed against any additional ESRD facility burden that could result from changes to claims and cost reporting.

e. Solicitation for Input and Comment: Improving Data Collection on Composite Rate Costs

In the CY 2020 ESRD PPS proposed rule (84 FR 38398), CMS solicited input on options for improving the reporting of composite rate costs for the ESRD PPS. We explained that we believed improved reporting of both patient level costs, as reported on claims, and facility level costs, as reported on cost reports, is needed in order to obtain sufficient, high quality data to inform a refined case mix adjusted model for the ESRD PPS. We solicited comments on, or elaborations of, the options presented and discussed during the TEP, described in the CY 2020 ESRD PPS proposed rule (84 FR 38396) and also in section VIII.A.1.b.ii of this final rule, as well as novel approaches for improving the reporting of patient-level and facility-level costs that are not described here. We stated that CMS will consider new input from stakeholders as we develop methodologies for implementing select changes to claims and cost reports that serve to elucidate composite rate costs. We noted that CMS has not endorsed any particular method or option at this time.

i. Input Sought on Identifying Components of Composite Rate Costs

During the TEP, the data contractor identified six cost components comprising composite rate costs for the ESRD PPS. These include: (1) Capital, (2) administrative, (3) labor, (4) drug, (5) laboratory and, (6) supply costs. Options were presented to improve the precision and accuracy of reporting costs for each component. Data on costs of some components, including capital, administrative and labor, are found chiefly in facility cost reports and reflect spending at the facility level. These facility-level costs, in combination with treatment counts can be used to estimate patient or treatment level composite rate costs. Data on other cost components, including drugs, laboratory tests and supplies, can be found both on the cost reports and on claims, however composite rate laboratory and supply costs are not specified on the cost report. Basic treatment charges are seen to vary little across patients or across facilities. Cost report data were questioned by the participants with regard to their accuracy and reliability.

Therefore, in the CY 2020 ESRD PPS proposed rule (84 FR 38398 through 38399), CMS solicited further input on ways to improve (1) the accuracy of charges and (2) the precision and reliability with which cost composite rate costs are identified and reported in cost reports.

We invited commenters to submit their responses to the following questions and requests:

- Do the six cost components include all aspects of dialysis treatment costs covered by Medicare?

++ If not, please describe any further component costs within each component?

++ Within each component, are there significant costs that are not currently captured in cost reports?

- The data contractor found that most composite rate costs are embedded in the capital, administrative and labor components. Given the relatively small contribution of drugs, laboratory tests, and supplies to composite rate costs, is there a justification for any further consideration of composite rate costs from capital, labor and administrative components?

- Why is there such limited variation in reported charges? Would it be useful to focus on improving reporting of these charges instead of collecting new information on cost reports or claims? Why is there such limited reporting of costs for items and services included in the CBL? Are there subsets of composite rate items and services that could be successfully reported on claims?

ii. Input Sought on Collection of Duration of Treatment Data

During the TEP, the data contractor proposed a paradigm by which to consider select changes to cost reporting that would reveal patient-level variation in costs, differentiating costs by those which can be attributed to dialysis treatment duration and those unrelated to treatment duration. Capturing data on these two types of differences was the thrust of the discussion during much of the TEP. In the CY 2020 ESRD PPS proposed rule (84 FR 38399), CMS solicited further input on these two elements of cost differential.

Dialysis session duration data could be used to refine calculations of per-treatment costs by increasing specificity in the allocation of composite rate costs. Applying this change only to current data collection practices would suffice to account for treatment level differences in costs due to length of

[46] Medicare Claims Processing Manual. Chapter 8—Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims. (Rev. 4202, 01–18–19). Page 7/143.

treatment. Duration data would allow for the distribution of composite rate component costs in such a way that a higher proportion of a facility's composite rate costs could be attributed to patients with longer dialysis treatment times. This would improve the precision with which costs for the use of such composite rate items and services as capital equipment use, water treatment and dialysate are allocated.

We invited comments on the option of collecting duration of treatments data, including responses to the following questions:

- Which of the six composite rate cost components (capital, administrative, labor, drug, laboratory, and supply costs) are most likely to vary with treatment duration?
- Should new information for these cost components be collected on cost reports, for use in better inferring the composite rate costs associated with treatment duration? If yes, please describe the additional information that would be needed and how this information could be used.
- Describe any challenges that would be encountered by ESRD facilities in reporting treatment duration, using a line item corresponding to units of time as a new revenue center code on the claim.
- Describe any alternatives to the use of dialysis treatment duration that could be used as a proxy for intensity of resource utilization and which can be reported at the patient/treatment level.
- Do facilities record the total time the patient spends in the facility before and after the actual dialysis treatment time, as well as the duration of the actual dialysis treatment? If so, please describe any obstacles to reporting this information on the claim.

iii. Input Sought on Collection of Data To Identify Sources of Variation in Treatment Costs Associated With Complex Patients

The data contractor presented a list of conditions, identified during pre-TEP interviews with ESRD facilities, associated with higher cost treatment for dialysis patients. During the TEP, the participants added to this list. The combined list of these conditions was described in the CY 2020 ESRD PPS proposed rule (84 FR 38397) and in section VIII.A.1.b.v of this final rule.

The data contractor also presented alternative approaches for collecting sufficient data on these composite rate costs so as to inform a refined case-mix model. One approach would entail reporting such items and services as line items on the claim. The second would involve grouping patients into a set of ''high risk'' or ''high cost'' patient types, in a hierarchical fashion, and apportioning costs to each patient grouping based on known use of services. There was no consensus among participants with regard to the best way to capture these costs.

In the CY 2020 ESRD PPS proposed rule (84 FR 38399), CMS solicited comments and suggestions about how to best capture these costs. In the proposed rule we provided the following questions to consider: First, to the extent labor is the dominant source of variation in cost in providing dialysis services to complex patients, please describe the amount and type of labor required to care for patients with the conditions described above or any other conditions which complicate the provision of basic dialysis treatment. Second, please describe other dimensions of dialysis care and treatment for which composite rate costs vary independent of treatment duration. Third, are there discrete, high-cost composite rate items and services that vary at the patient level that could be feasibly itemized on claims? Fourth, how could a set of mutually exclusive, exhaustive patient groups be constructed to incorporate patients with common patterns of resource use? Fifth, what challenges might be faced in implementing the proposed reporting solutions (a) on claims and (b) on cost reports? Sixth, are pediatric and home dialysis costs accurately apportioned across cost components in cost reports? If not, please describe.

iv. Input Sought on Collection of Facility-Level Data

During the TEP the data contractor presented a framework for considering facility-level drivers of cost, which meet two criteria: (i) They are independent of patient-level factors, and (ii) they affect the cost of dialysis treatment. The TEP debated each criterion for facility-level cost drivers, including facility size and realized treatment capacity. Geographic location affects wages and prices of goods and services. While some commenters have suggested that rural ESRD facilities incur higher costs, the data contractor's analysis of 2016 cost report data for the December 2018 TEP indicates that overall composite rate costs for rural facilities may be lower than for urban facilities. Further analysis by cost component suggests that with the exception of drug costs, urban facilities incur higher costs for each composite rate cost component. Ownership and other organizational factors, such as whether the facility administers a home dialysis program or serves the pediatric population also have a bearing on cost.

In the CY 2020 ESRD PPS proposed rule (84 FR 38399 through 38400), CMS solicited input from stakeholders regarding the further identification of facility-level drivers of cost, especially those that affect the cost of composite rate services. We asked commenters to consider the following questions: First, what facility level factors should be added or further specified in the cost report to better reflect actual facility costs for the provision of composite rate items and services? Second, what are costs incurred by pediatric dialysis units that do not vary at the patient-level? Third, what types of costs do facilities providing home dialysis services incur that do not vary at the patient-level? Fourth, how do variations in drivers of facility costs affect composite rate costs at the facility level? Fifth, to what extent are these composite rate costs outside the facility's control? Sixth, what are the challenges or barriers to reporting missed treatments on claims and/or cost reports?

v. Other Input Needed

In the CY 2020 ESRD PPS proposed rule (84 FR 38400), we also solicited responses to the following questions that arose during the TEP. We noted that answers to these questions from the stakeholder community will help us to develop and refine reporting options for composite rate costs.

Beginning January 1, 2015, ESRD facilities have been required to itemize on claims the use of composite rate drugs listed on the CBL.[47] As presented at the TEP, the data contractor's analysis of 2016 claims data revealed that approximately 40 percent of facilities were not reporting these items. We requested that commenters identify any obstacles that might be preventing ESRD facilities from reporting the use of these composite rate drugs. Also, are there any drugs listed in the most recent CBL that are particularly challenging to report? If there are, please describe those challenges.

The participants mentioned that Medicare Advantage and other secondary payers will sometimes reject claims that include billing for certain items and services, such as oral medications. We requested comments on the specific billing practices that lead to such claims being rejected, along with the specific items and services that are rejected by payers.

[47] Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978. December 2, 2014 (pp 3–4). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf.*

The participants expressed reservations about the reliability of cost report data and also about the comparability of cost reports between freestanding and hospital-based ESRD facilities.

We also solicited comments regarding suggested specific changes to the cost reports or cost report instructions that would be most useful to improve the consistency of reporting across facilities.

We received extensive comments on these issues from approximately 9 stakeholders and an additional 35 comments that indirectly addressed the request for information (RFI) for data collection. Below we provide a short synopsis of the findings for each of the topics discussed in the TEP and solicited for comment in the CY 2020 ESRD PPS proposed rule. We will provide a more detailed summary of the comments received on this RFI on the CMS website *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html*. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their detailed and thoughtful comments. We will consider these recommendations for future rulemaking.

Refinements to the Components of Composite Rate Costs

Some commentators expressed the opinion that use of composite rate components to price the cost of dialysis treatment was outmoded and counter to the objective of the bundled system instituted with the ESRD PPS in 2011. Although the RFI directed stakeholders to consider and comment on improving data collection for the determination of composite rate (CR) costs, the CR was not at the heart of their concerns. In fact, some commenters stated that the CR was an outmoded and unnecessary concept, dating back to the time before the implementation of the ESRD PPS in 2011, and attempts to discern individual cost components of the CR essentially served to ''unbundle'' the PPS. However, there was general support for improved reporting of patient level costs on claims and facility level costs on cost reports.

Several commenters objected to CMS' continued use of the two-equation payment model. They claimed the two equation model is flawed insofar as it uses facility level regression analysis of cost report data to determine the cost per treatment for CR services and the results from patient level regression analysis from data derived from claims to determine the average payment per patient for drugs, laboratory services and supplies. Multiplying factors from each regression model ''with different bases'' diminishes the accuracy of the model.

Little Variation Found in Charges

Commenters claimed that charges for individual treatments were hard, if not impossible, to capture and that doing so would represent an undue burden for facilities.

CMS' contractor analyzed charges for basic dialysis services, as they are reported on claims, and found little variation in charges either across patients within facilities or across facilities. Stakeholders were asked to comment on this phenomenon and provide explanation. Commenters responded by stating that variations in charges are inconsistent and [their occurrence is non-systematic] making it difficult to focus on assessing charges for the purposes of itemizing composite rate costs. Examples were provided for items and services that could vary by treatment, but which would be difficult to capture in charges. These included nurse training and the difficulty of separating nurse training hours from other hours worked. Others commented that it is not possible to assess specific items to include in charges for each dialysis treatment.

Patient-Level Factors Contributing to Higher Costs

With regard to patient-level factors contributing to high costs of care, commenters opined that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care. There was general agreement that adjustments for the use of isolation rooms for patients with active HBV infection and for patients in their initial months of dialysis treatment were warranted. Commenters opposed the use of dialysis treatment duration maintaining that other factors were more directly related to cost of treatment.

Commenters expressed the opinion that the cost report data was an inappropriate source from which to derive accurate patient-level adjusters from aggregated facility data, such as is recorded in the cost reports.

Commenters also asked to eliminate or significantly revise the current case mix adjusters. Commenters repeatedly expressed concerns that the methodology that was used to derive the case mix adjusters was flawed and not empirically based. Some commenters recommended the elimination of all the current case mix adjusters. Others suggested revisions, including removal of some adjusters. Some stated that case mix adjusters were not necessary and that they defeated the purpose of the bundled payment, effectively unbundling it. Others believed that the use of multiple adjusters that were highly correlated was problematic.

Another objection to the use of too many patient level adjusters related to the difficulty of obtaining accurate comorbidity data. Commenters stated that these diagnoses are made by medical providers, not by ESRD facility staff, and are contained in medical records which are not readily accessible by the ESRD facility. They claimed that the operational costs of claiming comorbidity payment adjustment exceeded the value of the adjustment.

In particular the use of age, BMI, and BSA was challenged. Commenters stated that there was no correlation between these factors and cost of dialysis treatment. Some commenters supported the use of patient-level cost factors that were presented at the 2019 TEP, including use of a catheter, non-ambulatory status, and some combined measure indicating behavioral, drug addiction or mental health problems, while others did not. Commenters endorsed the use of isolation rooms for patients with active HBV infection and an adjustment for patients in their initial period of dialysis.

The proposed use of duration of dialysis treatment time as a single, patient-level factor to estimate variation in CR costs was opposed. There was some indication that commenters thought that this method was being proposed in lieu of taking into account factors unrelated to treatment duration that made some patients more expensive to treat. Some commenters voiced the objection that use of this measure would not be productive because there was great homogeneity in treatment times across patients. Other commenters claimed that many subgroups of patients are challenged to stay on dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs and that these higher costs are related to patients' special circumstances and comorbidities and not to treatment duration.

Facility Level Adjusters and Suggested Changes to Cost Reports

With regard to facility-level factors driving costs, commenters agreed that the LVPA and rural adjustments needed refinement. They also were in agreement in calling for ESRD network fees and all bad debt to be added to cost reports as revenue reductions. Finally there was generally agreement that cost

reports needed revisions to improve accuracy and consistency of reporting.

Commenters agreed that current cost reports omit several key cost components and that more could be done to clarify reporting requirements in the cost report instructions. In particular, the ESRD network fee and bad debt were mentioned by several stakeholders as factors missing from the cost reports. Virtually all commenters who addressed this issue urged the inclusion of the ESRD network fee as a revenue reduction in Worksheet D of the cost report. They claimed that facilities were losing millions of dollars in reimbursable costs due to the omission of the ESRD network fee.

Bad debt was another facility-level cost that commenters strongly believed should be included in the cost report. Bad debt was characterized by contractors as pervasive problem that results when beneficiaries who face financial challenges cannot meet their cost sharing obligations. Presently, CMS only reimburses for 65 percent of bad debt liability (or 98 percent of 65 percent, if sequestration is taken into account). Commenters requested that 100 percent of bad debt be reimbursed. Commenters expressed that this problem will be exacerbated as new, more expensive treatments and devices come on the market. Commenters expressed the opinion that omission of unrecoverable bad debt results in a distorted representation of ESRD facility economics.

Several stakeholders also suggested that other revenue reductions should be allowed on the cost reports, including costs related to the ESRD QIP and losses related to budget sequestration. Finally, commenters requested that the cap on reporting of administrative salaries be removed.

The Low Volume Payment Adjuster (LVPA) and the Rural Adjuster were mentioned by several commenters as being problematic. First, some commenters expressed the opinion that the two adjusters were ''overlapping'' and suggested that a single, tiered low volume and ''isolated facility'' adjusters would serve better to target supplemental payments where they were most needed. Others commented that the LVPA should be targeted at small and independent facilities, whose treatment costs were higher, rather than go to large dialysis organizations which are better able to absorb any excess costs in isolated less populated facilities and whose treatment costs in such facilities were lower than those incurred by independent facilities.

Home dialysis costs were mentioned by commenters as representing a cost component that has risen significantly in recent years. Commenters maintained that current allocation for facility level costs for home dialysis is not adequate due to higher costs for supplies and equipment and limited competition among vendors. Commenters stated that exacerbating this problem are training costs for the more highly skilled nurses required to train and attend to home dialysis beneficiaries, as well as survey and certification requirements.

Finally, hospital and freestanding facility costs are seen by commenters to be vastly different with hospitals incurring higher costs due to a ''more intensive cost structure and/or clinically complex patient population'' compared to freestanding facilities. Additionally higher costs may be an artifact of the peculiar structure of the hospital based ESRD cost report. Commenters suggested that revisions be made to correct data reporting and structural problems in the cost report. Commenters also expressed support for more granular reporting of costs in cost reports.

Reporting of Composite Rate Items on the Consolidated Billing List

Commenters expressed that the lack of availability of HCPCS codes for oral drugs prevent their reporting on claims.

Stakeholders were asked to comment on why so few facilities reported on the use of composite rate drugs that appeared on the Consolidated Billing List, as has been required since 2015. Responders stated that many oral medications do not have HCPCS codes that would allow them to be itemized on claims and if claims are submitted to Medicare Advantage, including these items, the entire claim is rejected. Please see the Billing Practices section below for a further explanation of the consequences faced when such items are included on claims.

Billing Problems and Medicare Advantage

Commenters stated that Medicare Advantage and some other secondary payers rejected claims if they included certain items, including oral medications which did not have a HCPCS code.

Commenters mentioned several problems with Medicare Advantage (MA) billing practices for dialysis services. They stated that some MA plans will reject certain claims for a variety of reasons. Commenters reiterated the case made by panelists at the 2019 TEP that claims would be rejected by Medicare Advantage and other secondary payers if they contained certain drugs, including those that do not have HCPCS codes, as mentioned above, and in certain cases will not make separate payment to facilities for their provision of the TDAPA-eligible drugs. Commenters also stated that Medicare Advantage plans will reject claims that include more than 13 treatments per month, even when medically justified. This includes both in-center and home dialysis treatments. Commenters claimed that these practices discourage providers from offering home dialysis as a treatment option because of substantial increases in supply costs in recent years. Commenters also mentioned that MA plans often reject claims for dialysis treatments for beneficiaries traveling outside of the plan's network, having the unintentional result of restricting beneficiaries' ability to travel. Finally, commenters noted that Medicare Advantage plans do not always pay applicable payment adjustments for patients whose care otherwise is eligible for such adjustments. For example, MA plans do not always provide for the additional costs attendant to caring for patients in their first months of dialysis treatment, nor for the extra care required for patients with complex comorbidities.

Special Consideration: Pediatric Dialysis Facilities

Commenters highlighted that pediatric dialysis facilities are a special case, that a pediatric case mix adjuster is warranted, and that significant revisions to cost reports should be made to allow for the true cost of providing care to this special population to be adequately reported.

The 2019 ESRD PPS TEP identified treatment and care for pediatric patients as a source of composite rate cost variation associated with providing care to more complex patients and called for further input on those costs. In response to the RFI, commenters itemized exceptional costs that were incurred by pediatric dialysis facilities, including the need for specialized staff, such as behavioral specialists, school liaisons and child life specialists. Additional expenses include a broad array of supplies and devices to accommodate a range of patient sizes. Commenters recommended that in addition to a pediatric case mix adjuster, CMS consider the additional capital and labor costs associated with pediatric patients and use these to formulate a more robust pediatric ESRD facility payment formula. Finally, they suggested that CMS consider alternative billing practices for pediatric facilities. They stated that these facilities are usually housed in children's hospitals which do

not have experience with Medicare billing and reporting and lack the infrastructure to bill or provide required data accordingly.

B. Wage Index Comment Solicitation

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38359 through 38360) and in section II.B.5.b of this final rule, historically, we have calculated the ESRD PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the ESRD PPS wage index values and their impact on payments. In the CY 2020 ESRD PPS proposed rule (84 FR 38400), we solicited comments on concerns stakeholders may have regarding the wage index used to adjust the labor-related portion of the ESRD PPS base rate and suggestions for possible updates and improvements to the geographic wage index payment adjustment under the ESRD PPS.

We received comments on this topic from approximately 6 stakeholders. Below we provide summaries of the comments received in response to the solicitation in the CY 2020 proposed rule. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their detailed and thoughtful comments. We will consider these recommendations for future rulemaking.

Several commenters addressed the impact of data lag issues that they believe undermine the accuracy of the ESRD PPS wage indices. Under the current wage index methodology, CMS applies the most recent pre-floor, pre-classified hospital wage data collected annually under the Hospital IPPS. While commenters generally continue to support the methodology for determining the wage indices and the continued application of the wage index floor, they asked that CMS consider how the current policy could be modified to adjust wage index values to take into account laws requiring wage increases. They expressed that the wage index calculation data lag is particularly troublesome given higher wages due to state and municipality minimum wage actions and overall economic growth. They asserted that the current methodology will not capture these wage increases until years after their effect. They also noted that wage indices that do not reflect ESRD facilities' actual, current experience or the labor resources necessary to fulfill obligations under the Five-Star Quality Rating System and QIP will devalue the labor-related portion of the ESRD PPS base rate and inappropriately constrain ESRD PPS payments.

Commenters noted that under the current methodology, there can be a several year lag with the wage index recognizing these changes. They urged CMS to work to minimize the data lag and ensure the expeditious incorporation of current state and municipality minimum wage requirements and overall labor market trends that influence labor costs into the wage indices' calculation.

One healthcare organization commented on CMS' proposal, in section II.B.5.b of the CY 2020 ESRD PPS proposed rule, to continue to use the pre-floor, pre-reclassified hospital wage index for ESRD services in CY 2020. The healthcare organization said that it understood that, until CMS is able to develop a wage index system for ESRD, CMS will need to use a proxy such as the hospital wage index. However, the organization does not agree with using the pre reclassified wage index values. Hospitals are regularly allowed to reclassify to higher wage index areas which results in higher payment rates. Because ESRD providers compete with local hospitals for staff, the payment differentials allow hospitals to offer higher compensation than can be maintained in a nonhospital setting. As a result, the healthcare organization stated, other providers such as ESRD facilities are at a disadvantage when competing for nursing staff. Rather than contributing to the disparities between facilities, the healthcare organization recommended that CMS equalize the wage index rates between hospitals and ESRD providers that utilize the hospital wage index by using the post floor, post-reclassification wage index for each CBSA.

A national dialysis association stated that CMS should not apply any wage index changes associated with the IPPS final rule without undergoing notice-and-comment rulemaking in an ESRD PPS proposed rule. The association explained that the wage index promulgated in the IPPS impacts the base rate for the ESRD PPS since the labor-related portion of the ESRD PPS base rate is adjusted to account for geographic differences in the area wage levels. The association noted that the ESRD wage-index is based on the hospital index and utilizes pre-floor hospital data that are unadjusted for occupational mix. In addition to the hospital wage index being a critical component of the ESRD PPS base rate calculation, it also influences some of the facility-level adjusters, including the low-volume payment adjustment and the rural adjustment.

A professional association requested that CMS consider any such wage index changes in connection with any potential broad refinements to the ESRD PPS. The professional association recommended using a similar approach as the RFI for Data Collection because experiences of its members indicate that cost of care varies most by the patient's individual characteristics, comorbidities and psychosocial factors—as well as the relative severity of those individual comorbidities and psychosocial factors.

The association also noted that small and independent ESRD facilities typically have higher labor costs than larger dialysis organizations because of the generally higher proportion of skilled labor used in care delivery. The association urged CMS to formally recognize in the ESRD PPS the disproportionately higher labor costs borne by small and independent facilities as it considers possible changes to the ESRD PPS wage index.

The association also expressed that rural regions tend to experience higher labor costs than facilities in non-rural areas due to their difficulty in attracting labor. It noted that challenges in attracting qualified labor to care for the highly vulnerable ESRD patient population in rural areas are particularly acute given the overall shortage of nursing supply available and such issues have become even more critical with respect to attracting registered nurses and other clinical staff with experience in the provision of home dialysis—an expertise clearly sought after with the Administration's important initiatives to increase rates of home dialysis in ESRD treatment. Moreover, the association stated, if rural facilities are not able to find permanent staff locally, they must pay the associated travel costs and wages for travel time for staff traveling from units outside of the area qualified to treat patients. The association noted that these staffing challenges raise labor costs for rural providers, increasing their overall costs to provide high-quality care for patients. The association therefore asked CMS to formally account for the additional financial burden rural providers face in securing qualified labor to meet ESRD patient care needs in any changes considered for the ESRD PPS wage index.

The association further suggested that as CMS considers possible changes to the ESRD PPS wage index, CMS examines how and why these two approaches of calculating the labor-related share have varied over time. The association stated that such examination may provide useful information about the specific approach to measurement

and/or quality of the underlying data under either method, and could offer useful insights about the implications for the cost-side data sources utilized for any potential refinement to the ESRD PPS.

C. Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries (Section 50414 of the Bipartisan Budget Act of 2018)

1. Background

Section 1847(a)(2)(A) of the Act mandates competitive bidding programs for ''covered items'' and supplies used in conjunction with DME such as blood glucose monitors used by beneficiaries with diabetes. The supplies used with these blood glucose monitors (such as blood glucose test strips and lancets) are referred to under the DMEPOS CBP as diabetic supplies or diabetic testing supplies. In the April 10, 2007 final rule published in the **Federal Register** titled ''Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'' (72 FR 17992), which implemented the DMEPOS CBP, we established regulations to implement competitions on a regional or national level for certain items such as diabetic testing supplies that are furnished on a mail order basis. We explained our rationale for establishing a national DMEPOS CBP for items furnished on a mail order basis in the May 1, 2006 proposed rule published in the **Federal Register** titled ''Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'' (71 FR 25669) and in the April 2007 final rule (72 FR 18018).

On January 16, 2009, we published an interim final rule in the **Federal Register** titled ''Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)'' that implemented certain changes to the DMEPOS CBP (74 FR 2873). Specifically, the rule implemented section 154 of MIPPA (Pub. L. 110–275), which delayed implementation of Round One of the program, required CMS to conduct a second Round One competition in 2009, and mandated certain changes for both the Round One Rebid and subsequent rounds of the program. In the January 2009 interim final rule, we indicated that we would be considering alternatives for competition of diabetic testing supplies in future notice and comment rulemaking.

On July 13, 2010 we published a proposed rule in the **Federal Register** titled ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011'' (75 FR 40211), in which we discussed alternatives for competition of diabetic testing supplies and proposed the implementation of a revised national mail order CBP for diabetic testing supplies. Under the proposed mail order DMEPOS CBP, we would award contracts to suppliers to furnish these items across the nation to beneficiaries who elect to have replacement diabetic testing supplies delivered to their residence. Suppliers wishing to furnish these items through the mail to Medicare beneficiaries would be required to submit bids to participate in the national mail order CBP for diabetic testing supplies.

Section 154(d) of MIPPA modified section 1847(b)(10) of the Act to prohibit CMS from awarding a contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of all types of diabetes test strips on the market. With respect to any competition for diabetic testing strips after the first round of competition, a supplier must demonstrate that its bid to furnish diabetic testing strips covers the types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover at least 50 percent of all such types of products on the market. CMS and the CBIC refer to this rule as the ''50 percent rule.'' [48] Section 1847(a)(10)(A) of the Act also specified that the volume for the different products may be determined in accordance with data (which may include market based data) recognized by the Secretary.

Section 1847(b)(10)(B) of the Act mandated that the Office of Inspector General (OIG) conduct a study before 2011 to determine the types of diabetic testing strips by volume that could be used by CMS for the purpose of evaluating bidders in the national mail order CBP for diabetic testing supplies. Under the DMEPOS CBP, bidding suppliers are required to provide information on the products they plan to furnish if awarded a contract. We proposed in the July 2010 proposed rule (75 FR 40211) to use information submitted by bidding suppliers and information on the market share (volume) of the various diabetic testing strip products to educate suppliers on meeting the requirements of this special 50 percent rule. We noted that it may be necessary to obtain additional information from suppliers such as invoices or purchase orders to verify that the requirements in the statute have been met (75 FR 40214). We proposed that suppliers be required to demonstrate that their bids cover the minimum 50-percent threshold provided in the statute, but we invited comments on whether a higher threshold should be used (75 FR 40214). We proposed the 50 percent threshold in part because we believed that all suppliers have an inherent incentive to furnish a wide variety of types of diabetic testing products to generate a wider customer referral base (75 FR 40214). The 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top-selling diabetic test strip products (75 FR 40214). In addition, we proposed an ''anti-switching provision'' that we said would obviate the need to establish a threshold of greater than 50 percent for the purpose of implementing this special rule because the contract suppliers would not be able to carry a limited variety of products and switch beneficiaries to those products (75 FR 40214). For purposes of implementing the special rule in section 1847(b)(10)(A) of the Act, we proposed to define ''diabetic testing strip product'' as a specific brand and model of test strip, as we said that was the best way to distinguish among different products (75 FR 40214). Therefore, we planned to use market based data for specific brands and models of diabetic test strips to determine the relative market share or volume of the various products on the market that are available to Medicare beneficiaries (75 FR 40214). We stated we would apply this rule to non-mail order competitions and/or local competitions conducted for diabetic testing strips after Round One of the DMEPOS CBP (75 FR 40214).

In the November 29, 2010 final rule with comment period published in the **Federal Register** titled ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011'' (75 FR 73567), we established requirements for the national mail order CBP for diabetic testing supplies. We finalized the proposed special 50 percent rule mandated by section 1847(b)(10)(A) of the Act (75 FR 73611). We finalized our proposal to require each bidder in the national mail order CBP for diabetic

[48] *https://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf/$FIle/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf.*

testing supplies to demonstrate that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products (75 FR 73611). We stated that the 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top selling diabetic test strip products from every contract supplier, and we adopted the 50 percent rule because we believed this was reflective of what suppliers were currently doing and ensured appropriate access for beneficiaries (75 FR 73611). We also stated that the OIG was conducting a study to generate volume data for various diabetic testing strip products furnished on a mail order basis (75 FR 73572). We stated that we would use this data as guidance to implement this special rule for mail order contract suppliers and ensure that their bids cover at least 50 percent of the volume of testing strip products currently furnished to beneficiaries via mail order (75 FR 73572). The OIG was required to complete their study before 2011 and we said we would make their data available to the public (75 FR 73572).

The OIG released its study in 2010, and the OIG has since determined the market shares of the types of diabetes test strips before each round of competitive bidding. The data from this series of reports informs CMS about the types of diabetes test strips that suppliers provide to Medicare beneficiaries via mail order.

Current Issues

The Bipartisan Budget Act of 2018 (BBA) was enacted on February 9, 2018, and section 50414 of the BBA amended section 1847(b)(10)(A) of the Act to establish additional rules for the competition for diabetic testing strips. Section 1847(b)(10)(A) of the Act now requires that for bids to furnish diabetic testing strips on or after January 1, 2019, the volume for such products be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

The OIG reports to CMS the Medicare Part B market share of mail order diabetic test strips before each round of the Medicare national mail order CBP, and pursuant to section 1847(b)(10)(A) of the Act, the OIG will now report on the non-mail order diabetic test strip Medicare Part B market. On January 19, 2019, the OIG released a report that documented the Medicare Part B market share of mail order diabetic test strips for the 3-month period of April through June 2018.[49] On March 19, 2019, the OIG released another report that documented the Medicare Part B market share of non-mail-order diabetic test strip for the same 3-month period.[50] These data briefs represent OIG's third round of diabetic test strip Medicare market share reports since 2010, but this is the first series of reports that includes non-mail-order diabetic test strip data.

Because section 1847(b)(10)(A) of the Act now requires the use of ''multiple sources of data,'' we requested public comments on other potential sources of data (sources other than the OIG), that fulfill the data requirements set forth in section 1847(b)(10)(A) of the Act. We requested comments on other potential sources of data because the word ''multiple'' in the phrase ''multiple sources of data'' could mean that we should use more than one source of data, and that the OIG is one source of data. We therefore requested comments from the public on other potential sources of data regarding the mail order and non-mail order Medicare markets for diabetic testing strips through this request for information. In particular, we sought data that:

- Has a sufficient sample size, and is unbiased and credible;
- Separately provides the market shares of the mail-order Medicare Part B market, and the non-mail order Medicare Part B market (does not combine the two markets into one); and
- Includes market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

We received 6 comments from suppliers, industry representative groups, and others in response to this Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries. Of the comments we received, none included data, or readily available sources of data, and were otherwise outside the scope of the request for information.

The comments received in response to the Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries are set forth below.

A few commenters recommended that CMS require suppliers to bill as they do for Medicare Part D. The commenters said that Part D billing allows for on-line claim adjudication, requiring that suppliers bill with a National Drug Code (NDC) product number so CMS can collect that data (the commenter recognized that there may be Paperwork Reduction Act issues). The commenters said that any survey of current Medicare Part B claims for diabetic testing strips would not accurately represent the overall market because reduced payment rates have caused suppliers to offer beneficiaries fewer product options. The commenters went on to say that the challenge with requesting this utilization information from manufacturers is that manufacturers do not know who will be paying for the product, and that manufacturer sales data is therefore not representative of products provided to Medicare beneficiaries.

One commenter said that CMS should only consider data for brands obtained under Medicare Part B, and that CMS should not consider diabetic testing supplies obtained through Part C or D because many of the supplies provided under Part C or Part D are on the formulary of the private insurance company. The commenter also stated that providers in the previous national mail order CBP did not have contracts with certain test strip manufacturers, as these manufacturers shut out the mail order providers in an attempt to drive patients to a pharmacy where they were able to work within the pharmacy benefit manager rebate programs. Another commenter said that information about access to certain test strip brands are potentially inaccurate, because some brands only contracted with certain national mail order CBP providers.

We appreciate the range of the comments we received. We will consider these comments carefully as we contemplate future policies.

IX. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. We solicited comments in the proposed rule, which published in the **Federal Register** on August 6, 2019 (84 FR 38330 through 38421). For the purpose of transparency, we are republishing the discussion of the information collection requirements. All of the requirements discussed in this

[49] *https://oig.hhs.gov/oei/reports/oei-04-18-00440.pdf.*

[50] *https://oig.hhs.gov/oei/reports/oei-04-18-00441.pdf.*

section are already accounted for in OMB approved information requests.

B. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purpose of the data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. The mean hourly wage of a Medical Records and Health Information Technician is $21.16 per hour.[51] Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $42.32 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts as well as a refined estimate of the time spent completing data entry for reporting data, to re-estimate the total information collection burden in the ESRD QIP for PY 2022 that we discussed in the CY 2019 ESRD QIP final rule (83 FR 57050 through 57052) and to estimate the total information collection burden in the ESRD QIP for PY 2023. We provide the re-estimated information collection burden associated with the PY 2022 ESRD QIP and the newly estimated information collection burden associated with the PY 2023 ESRD QIP in sections IV.C.2 and IV.C.3 of this final rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2022 and PY 2023

In the CY 2019 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities would be selected each year to submit to CMS not more than 10 records, and we would reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimated that the aggregate cost of the CROWNWeb data validation each year will be approximately $30,885 (750 hours × $41.18), or an annual total of approximately $103 ($30,885/300 facilities) per facility in the sample. In this final rule, we are updating these estimates using a newly available wage estimate of a Medical Records and Health Information Technician and have made no other changes to our methodology for calculating the annual burden associated with the CROWNWeb validation study. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately $31,740 (750 hours × $42.32), or an annual total of approximately $105.80 ($31,740/300 facilities) per facility in the sample. The increase in our burden estimate is due to an updated wage estimate for Medical Records and Health Information Technicians or similar staff and is not the result of any policies finalized in this final rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

In section IV.D.5 of this final rule, we are finalizing that we will continue in PY 2023 and subsequent payment years the NHSN data validation study using the methodology finalized in the CY 2019 ERD PPS final rule for PY 2022 (83 FR 57001 through 57002) and adopt the NHSN validation study as a permanent feature of the ESRD QIP. Under this methodology, we will select 300 facilities for participation in the PY 2023 validation study. A CMS contractor will send these facilities requests for 20 patients' records for each of the first 2 quarters of CY 2021 (for a total of 40 patient records per facility). The burden associated with these data validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. Using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that it will take each facility approximately 10 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 3,000 hours (300 facilities × 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff will submit these data, we estimate that the aggregate cost of the NHSN data validation each year will be approximately $126,960 (3,000 hours × $42.32), or a total of approximately $423.20 ($126,960/300 facilities) per facility in the sample. The increase in our burden estimate is due to an updated wage estimate for Medical Records and Health Information Technicians or similar staff and is not the result of any policies finalized in this final rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1340).

3. CROWNWeb Reporting Requirements for PY 2022 and PY 2023

To determine the burden associated with the CROWNWeb reporting requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In the CY 2019 ESRD

[51] *https://www.bls.gov/oes/current/oes292071.htm.*

PPS final rule, we estimated that the burden associated CROWNWeb reporting requirements for the PY 2022 ESRD QIP was approximately $202 million. We did not propose in the CY 2020 ESRD PPS proposed rule any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2022 or PY 2023. However, we re-calculated the burden estimate for PY 2022 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. In the CY 2019 ESRD PPS final rule, we estimated that the amount of time required to submit measure data to CROWNWeb was 2.5 minutes per element and used a rounded estimate of 0.042 hours in our calculations. In the proposed rule and in this final rule, we did not use a rounded estimate of the time needed to complete data entry for CROWNWeb reporting. Based on the updated estimates that we used to re-calculate the burden estimate for PY 2022, we estimate that the PY 2022 burden is $211 million (or 4.8 million hours), and the net incremental burden from PY 2022 to PY 2023 is $0 (or 0 hours).

X. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicited comments on the regulatory impact analysis provided. With regard to the ESRD PPS, we did not receive any comments on the RIA.

2. Statement of Need

a. ESRD PPS

This rule finalizes a number of routine updates and several policy changes to the ESRD PPS in CY 2020. The finalized routine updates include the CY 2020 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to ESRD patients.

b. AKI

This rule also finalizes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule finalizes updates to the ESRD QIP, including a modification to the scoring methodology for the NHSN Dialysis Event reporting measure beginning with the PY 2022 ESRD QIP; the conversion of the STrR clinical measure to a reporting measure; and the adoption of the NHSN validation study as a permanent feature of the program using the methodology finalized for the PY 2022 NHSN validation study. In addition, we finalized that for all clinical measures in PY 2023 ESRD QIP, CY 2021 would be the performance period, CY 2020 would be the baseline period used to establish the improvement thresholds, and CY 2019 would be used for establishing the achievement thresholds, benchmarks, and minimum TPS. For future ESRD QIP payment years, we finalized that we would adopt automatically a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule finalizes a gap-filling methodology for new DMEPOS items and services.

ii. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

This rule finalizes a method for making a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts.

e. Conditions of Payment To Be Applied to Certain DMEPOS Items

This final rule will streamline the requirements for ordering DMEPOS items. It would also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

3. Overall Impact

a. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $210 million in payments to ESRD facilities in CY 2020, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and the change in the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to

ASP+0 percent. These figures do not reflect estimated increases or decreases in expenditures based on the refinement to the TDAPA eligibility criteria, conditioning the TDAPA on ASP data availability, or providing the TPNIES. The fiscal impact of these policies cannot be determined due to the uniqueness of the new renal dialysis drugs and biological products and new renal dialysis equipment and supplies eligible for these add-on payment adjustments and their costs.

b. AKI

We are estimating approximately $40 million that will now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

c. ESRD QIP

For PY 2022, we have re-estimated the costs associated with information collection requirements under the Program with updated estimates of the total number of dialysis facilities, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. We have made no other changes to our methodology for calculating the annual burden associated with the information collection requirements for with the CROWNWeb validation study, the NHSN validation study, and CROWNWeb reporting. None of the policies finalized in this final rule will affect our estimates of the annual burden associated with the Program's information collection requirements.

We also re-estimated the payment reductions under the ESRD QIP to correct an error in the way the weights were redistributed when estimating the PY 2022 payment reductions for the CY 2019 ESRD PPS final rule (83 FR 57060) and in accordance with the finalized policy changes described earlier, including the changes to the scoring methodology for the NHSN Dialysis Event reporting measure and the conversion of the STrR measure from a clinical measure to a reporting measure. We also updated the payment reduction estimates using newly available data for the PPPW clinical measure and the Ultrafiltration reporting measure and more recent data for the other measures in the ESRD QIP measure set. We estimate that these updates will result in an overall impact of $229 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule, which includes an estimated $211 million in information collection burden and an additional $18 million in estimated payment reductions across all facilities, for PY 2022.

For PY 2023, we estimate that the finalized revisions to the ESRD QIP will result in an overall impact of $229 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule, which includes an $18 million in estimated payment reductions across all facilities.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services

This final rule establishes a gap-filling methodology for new items and services. The fiscal impact of the gap-filling methodology cannot be determined due to the uniqueness of potential new DMEPOS items and their costs.

ii. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

While these adjustments will decrease fee schedule amounts that have been established using supplier or commercial prices by less than 15 percent, the savings are considered a small offset to the potential increase in costs of establishing fee schedule amounts based on supplier invoices or prices from commercial payers. The fiscal impact for this provision is therefore considered negligible.

e. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule finalizes to streamline the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's final rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed comments on the approach in estimating the number of entities, which will review this final rule. We did not receive any comments on this section on the rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption. We did not receive any comments on this section on the rule.

Using the wage information from the Bureau of Labor Statistics (BLS) (*https://www.bls.gov/oes/2018/may/naics4_621100.htm*) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.00 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this final rule. For each ESRD facility that reviews the rule, the estimated cost is $687.50 (6.25 hours × $110.00). Therefore, we estimate that the total cost of reviewing this regulation rounds to $107,250. ($687.50 × 156 reviewers).

For manufacturers of DMEPOS products, DMEPOS suppliers, and other DMEPOS industry representatives, we calculate a different cost of reviewing this rule. Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review this final rule. For each entity that reviews this final rule, the estimated cost is $110.00. Therefore, we estimate that the total cost of reviewing this rule is $71,500 ($110.00 × 650 reviewers).

B. Detailed Economic Analysis

1. CY 2020 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2019 to estimated payments in CY 2020. To estimate the impact among various types of ESRD facilities, it is imperative that the

estimates of payments in CY 2019 and CY 2020 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2018 data from the Part A and Part B Common Working Files as of September 18, 2019, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2018 claims to 2019 and 2020 using various updates. The updates to the ESRD PPS base rate are described in section II.B.5.d of this final rule. Table 14 shows the impact of the estimated CY 2020 ESRD payments compared to estimated payments to ESRD facilities in CY 2019.

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TABLE 14: Impact of Finalized Changes in Payment to ESRD Facilities for CY 2020

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Effect of 2020 Changes in Outlier Policy (C)	Effect of 2020 Changes in Wage Index (D)	Effect of 2020 Changes in Payment Rate Update (E)	Effect of Changes in TDAPA (F)	Effect of Total 2020 Final Changes (G)
All Facilities	7,442	45.2	0.4%	0.0%	1.7%	-0.4%	1.6%
Type							
Freestanding	7,050	43.2	0.4%	0.0%	1.7%	-0.4%	1.6%
Hospital based	392	2.0	0.8%	0.0%	1.7%	-0.3%	2.1%
Ownership Type							
Large dialysis organization	5,698	35.1	0.4%	0.0%	1.7%	-0.4%	1.6%
Regional chain	930	5.7	0.4%	0.1%	1.7%	-0.5%	1.7%
Independent	502	2.9	0.4%	0.0%	1.7%	-0.4%	1.7%
Hospital based[1]	304	1.5	0.8%	0.0%	1.7%	-0.3%	2.2%
Unknown	8	0.0	1.3%	-0.8%	1.7%	-0.2%	2.1%
Geographic Location							
Rural	1,289	6.5	0.4%	0.1%	1.7%	-0.4%	1.8%
Urban	6,153	38.6	0.4%	0.0%	1.7%	-0.4%	1.6%
Census Region							
East North Central	1,195	6.2	0.4%	-0.2%	1.7%	-0.4%	1.5%
East South Central	589	3.3	0.4%	0.0%	1.7%	-0.5%	1.5%
Middle Atlantic	811	5.5	0.4%	-0.1%	1.7%	-0.4%	1.6%
Mountain	410	2.3	0.3%	0.0%	1.7%	-0.3%	1.7%
New England	198	1.4	0.4%	-0.5%	1.7%	-0.4%	1.2%
Pacific[2]	881	6.5	0.4%	0.5%	1.7%	-0.3%	2.2%
Puerto Rico and Virgin Islands	47	0.3	0.2%	-0.1%	1.7%	-0.3%	1.4%
South Atlantic	1,713	10.7	0.4%	-0.1%	1.7%	-0.5%	1.5%
West North Central	512	2.3	0.5%	0.3%	1.7%	-0.4%	2.1%
West South Central	1,086	6.6	0.4%	0.0%	1.7%	-0.5%	1.6%
Facility Size							
Less than 4,000 treatments	1,385	2.1	0.4%	0.0%	1.7%	-0.3%	1.8%
4,000 to 9,999 treatments	2,804	12.3	0.4%	0.0%	1.7%	-0.4%	1.7%
10,000 or more treatments	3,219	30.7	0.4%	0.0%	1.7%	-0.4%	1.6%
Unknown	34	0.1	0.4%	0.1%	1.7%	-0.6%	1.7%
Percentage of Pediatric Patients							
Less than 2%	7,338	44.8	0.4%	0.0%	1.7%	-0.4%	1.6%
Between 2% and 19%	41	0.3	0.5%	-0.1%	1.7%	-0.4%	1.7%
Between 20% and 49%	14	0.0	0.3%	0.0%	1.7%	-0.1%	1.9%
More than 50%	49	0.0	0.3%	-0.2%	1.7%	0.0%	1.8%

[1]Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2]Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.5.c of this final rule is shown in column C. For CY 2020, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.4 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2020 payments as a result of the final outlier policy changes.

Column D shows the effect of the final CY 2020 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.8 percent decrease to a 0.5 percent increase due to these final updates.

Column E shows the effect of the final CY 2020 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.7 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2020 of 2.0 percent and the final MFP adjustment of 0.3 percent.

Column F reflects the change in the payment of the TDAPA from ASP+6 percent to ASP+0 percent.

Column G reflects the overall impact, that is, the effects of the final outlier policy changes, the final wage index, payment rate update, and final TDAPA payment changes. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated payments in CY 2020. The categories of types of facilities in the impact table show impacts ranging from an increase of 1.2 percent to 2.2 percent in their CY 2020 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2020, we estimate that the final ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2020 would be approximately $10.3 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.4 percent in CY 2020.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.6 percent overall increase in the final CY 2020 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2020, which translates to approximately $40 million.

e. Alternatives Considered

i. Eligibility Criteria for the TDAPA

In section II.B.1 of this final rule, we finalized revisions to the drug designation process regulation for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. In an effort to support innovation in the renal dialysis space, while simultaneously considering the cost to Medicare, for the refinement of the TDAPA eligibility we considered limiting it to only the Type 1 NDA Classification Code, section 351(a) biological products and section 351(k) biosimilar or interchangeable biological products. However, we wanted to support other innovative changes of drugs and biological products in the renal dialysis space and acknowledge that innovation may occur incrementally.

ii. New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

In section II.B.3 of this final rule, we finalized to provide a transitional add-on payment adjustment to support the use of certain new and innovative renal dialysis equipment and supplies by ESRD facilities. With regard to pricing mechanisms for equipment and supplies, we considered alternatives such as those used in the DMEPOS program and consultation with the Pricing, Data, and Analysis Contractor. However, methodologies such as reasonable charges and use of fee schedules were lacking for many items and did not address the new and innovative renal dialysis equipment and supplies that we expect to be forthcoming with the KidneyX initiative.

2. Final Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2019 to estimated payments in CY 2020. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2019 and CY 2020 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2018 data from the Part A and Part B Common Working Files as of September 18, 2019, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2018 claims to 2019 and 2020 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 15 shows the impact of the estimated CY 2020 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2019.

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TABLE 15: Impact of Finalized Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2020

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of 2020 Changes in Wage Index (C)	Effect of 2020 Changes in Payment Rate Update (D)	Effect of Total 2020 Final Changes (E)
All Facilities	4,707	247.2	0.0%	1.7%	1.7%
Type					
Freestanding	4,585	243.1	0.0%	1.7%	1.7%
Hospital based	122	4.1	-0.1%	1.7%	1.6%
Ownership Type					
Large dialysis organization	3,934	209.1	0.0%	1.7%	1.7%
Regional chain	534	25.7	-0.1%	1.7%	1.6%
Independent	166	10.0	0.0%	1.7%	1.7%
Hospital based[1]	72	2.3	-0.1%	1.7%	1.6%
Unknown	1	0.0	0.5%	1.7%	2.2%
Geographic Location					
Rural	829	40.0	0.2%	1.7%	1.9%
Urban	3,878	207.2	0.0%	1.7%	1.7%
Census Region					
East North Central	849	47.2	-0.1%	1.7%	1.6%
East South Central	384	19.1	0.1%	1.7%	1.8%
Middle Atlantic	482	26.5	-0.3%	1.7%	1.4%
Mountain	283	15.8	-0.3%	1.7%	1.4%
New England	146	6.2	-0.6%	1.7%	1.1%
Pacific[2]	538	34.9	0.7%	1.7%	2.4%
Puerto Rico and Virgin Islands	2	0.0	0.0%	1.7%	1.7%
South Atlantic	1,097	56.1	-0.2%	1.7%	1.5%
West North Central	310	12.3	0.2%	1.7%	1.9%
West South Central	616	28.9	0.1%	1.7%	1.8%
Facility Size					
Less than 4,000 treatments	533	17.7	0.0%	1.7%	1.7%
4,000 to 9,999 treatments	1,875	90.9	0.0%	1.7%	1.7%
10,000 or more treatments	2,296	138.5	0.0%	1.7%	1.7%
Unknown	3	0.1	0.5%	1.7%	2.2%
Percentage of Pediatric Patients					
Less than 2%	4,706	247.2	0.0%	1.7%	1.7%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	1	0.0	-1.8%	1.7%	-0.1%

[1]Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2]Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B

indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the final CY 2020 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 1.8 percent decrease to a 0.7 percent increase due to these final updates.

Column D shows the effect of the final CY 2020 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.7 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2020 of 2.0 percent and the final MFP adjustment of 0.3 percent.

Column E reflects the overall impact, that is, the effects of the final wage index and payment rate update. We expect that overall ESRD facilities would experience a 1.7 percent increase in estimated payments in CY 2020. The categories of types of facilities in the impact table show impacts ranging from a 0.1 percent decrease to a 2.4 percent increase in their CY 2020 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are updating the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and his or her physician. Therefore, this update will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $40 million would be paid to ESRD facilities in CY 2020 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. We are finalizing in this final rule that we will convert the STrR clinical measure to a reporting measure, and also change the way the NHSN Dialysis Event reporting measure is scored. The general methodology that we are using to determine a facility's TPS is described in our regulations at § 413.178(d).[52]

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2022, as codified in our regulations at § 413.177.

For the PY 2022 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 26.1 percent or 1,871 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2022. The total payment reductions for all the 1,871 facilities expected to receive a payment reduction is approximately $18,247,083.76. Facilities that do not receive a TPS do not receive a payment reduction.

Table 16 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

TABLE 16: Estimated Distribution of PY 2022 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,293	73.88%
0.5%	1,339	18.69%
1.0%	432	6.03%
1.5%	81	1.13%
2.0%	19	0.27%

*223 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2022, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there

[52] We are redesignating § 413.178(d) as § 413.178(e) in this final rule.

were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 17) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 17. We also note that because we are finalizing in section IV.D.2.b of this final rule that we will convert the STrR measure from a clinical measure to a reporting measure, the STrR measure is no longer listed in Table 17.

TABLE 17: Data Used to Estimate PY 2022 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, medians (50th percentiles of the national performance), benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SHR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
%Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR, facilities were required to have at least 5 at risk patients, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.D of this final rule. Facility reporting measure scores were estimated using available data from CY 2018. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2022 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 18 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2022 ESRD QIP, the actual impact of the PY 2022 ESRD QIP may vary significantly from the values provided here.

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TABLE 18: Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2022

	Number of Facilities	Number of Treatments 2018 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,386	44.6	7,164	1,871	-0.17%
Facility Type:					
Freestanding	6,995	42.7	6,807	1,764	-0.17%
Hospital-based	391	1.9	357	107	-0.23%
Ownership Type:					
Large Dialysis	5,603	34.5	5,487	1,286	-0.15%
Regional Chain	927	5.7	897	264	-0.19%
Independent	512	2.9	490	227	-0.36%
Hospital-based (non-chain)	305	1.5	276	87	-0.25%
Unknown	39	0.0	14	7	-0.32%
Facility Size:					
Large Entities	6,530	40.2	6,384	1,550	-0.15%
Small Entities[1]	817	4.4	766	314	-0.32%
Unknown	39	0.0	14	7	-0.32%
Rural Status:					
1) Yes	1,285	6.5	1,242	158	-0.08%
2) No	6,101	38.2	5,922	1,713	-0.19%
Census Region:					
Northeast	1,004	6.9	976	250	-0.16%
Midwest	1,696	8.4	1,637	418	-0.17%
South	3,360	20.4	3,244	964	-0.20%
West	1,271	8.6	1,252	197	-0.09%
US Territories[2]	55	0.4	55	42	-0.51%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,141	329	-0.20%
East South Central	587	3.3	579	146	-0.16%
Middle Atlantic	806	5.4	781	221	-0.18%
Mountain	409	2.3	404	60	-0.10%
New England	198	1.4	195	29	-0.08%
Pacific	862	6.3	848	137	-0.09%
South Atlantic	1,699	10.5	1,650	536	-0.22%
West North Central	508	2.2	496	89	-0.11%
West South Central	1,074	6.6	1,015	282	-0.18%
US Territories[2]	47	0.3	47	40	-0.58%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,117	230	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	510	-0.12%
Over 10,000 treatments	3,159	29.8	3,149	1,019	-0.20%
Unknown	377	0.5	278	112	-0.37%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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b. Effects of the PY 2023 ESRD QIP on ESRD Facilities

For the PY 2023 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 26.1 percent or 1,871 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. The total payment reductions for all the 1,871 facilities expected to receive a payment reduction is approximately $18,247,083.76. Facilities that do not receive a TPS do not receive a payment reduction.

Table 19 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 19: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,293	73.88%
0.5%	1,339	18.69%
1.0%	432	6.03%
1.5%	81	1.13%
2.0%	19	0.27%

*223 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 19) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 20. We also note that because we are finalizing in section IV.D.2.b of this final rule that we will convert the STrR measure from a clinical measure to a reporting measure, the STrR measure is no longer listed in Table 20.

TABLE 20: Data Used to Estimate PY 2023 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
%Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR, facilities were required to have at least 5 at-risk patients, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the policies finalized in section IV.D and IV.E of this final rule. Facility reporting measure scores were estimated using available data from CY 2018. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 21 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2023. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by

number of treatments per facility), geography (both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period that we are finalizing to use for the PY 2023 ESRD QIP, the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided here.

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TABLE 21: Impact of QIP Payment Reductions to ESRD Facilities for PY 2023

	Number of Facilities	Number of Treatments 2017 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,386	44.6	7,164	1,871	-0.17%
Facility Type:					
Freestanding	6,995	42.7	6,807	1,764	-0.17%
Hospital-based	391	1.9	357	107	-0.23%
Ownership Type:					
Large Dialysis	5,603	34.5	5,487	1,286	-0.15%
Regional Chain	927	5.7	897	264	-0.19%
Independent	512	2.9	490	227	-0.36%
Hospital-based (non-chain)	305	1.5	276	87	-0.25%
Unknown	39	0.0	14	7	-0.32%
Facility Size:					
Large Entities	6,530	40.2	6,384	1,550	-0.15%
Small Entities[1]	817	4.4	766	314	-0.32%
Unknown	39	0.0	14	7	-0.32%
Rural Status:					
1) Yes	1,285	6.5	1,242	158	-0.08%
2) No	6,101	38.2	5,922	1,713	-0.19%
Census Region:					
Northeast	1,004	6.9	976	250	-0.16%
Midwest	1,696	8.4	1,637	418	-0.17%
South	3,360	20.4	3,244	964	-0.20%
West	1,271	8.6	1,252	197	-0.09%
US Territories[2]	55	0.4	55	42	-0.51%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,141	329	-0.20%
East South Central	587	3.3	579	146	-0.16%
Middle Atlantic	806	5.4	781	221	-0.18%
Mountain	409	2.3	404	60	-0.10%
New England	198	1.4	195	29	-0.08%
Pacific	862	6.3	848	137	-0.09%
South Atlantic	1,699	10.5	1,650	536	-0.22%
West North Central	508	2.2	496	89	-0.11%
West South Central	1,074	6.6	1,015	282	-0.18%
US Territories[2]	47	0.3	47	40	-0.58%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,117	230	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	510	-0.12%
Over 10,000 treatments	3,159	29.8	3,149	1,019	-0.20%
Unknown	377	0.5	278	112	-0.37%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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c. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmission Reduction Program and the Hospital-Acquired Conditions Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

d. Effects on the Medicare Program

For PY 2023, we estimate that the ESRD QIP will contribute approximately $18,247,083.76 in Medicare savings. For comparison, Table 19 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2023. We note that Table 22 contains a lower estimated payment reduction for PY 2022 than we included in Table 49 of the CY 2019 ESRD PPS final rule (83 FR 57061).

TABLE 22: Estimated Payment Reductions Payment Years 2018 through 2023

Payment year	Estimated payment reductions
PY 2023	$18,247,083.76
PY 2022	$18,247,083.76
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

e. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

f. Alternatives Considered

In response to the concern raised by commenters about the validity of the modified STrR measure, we considered aligning the STrR measure's specifications with those used for the measure prior to the PY 2021 ESRD QIP. However, that version of the STrR clinical measure was not endorsed by the NQF due to the concern expressed by the Renal Standing Committee about variability in hospital coding practices.

4. DMEPOS

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

(1) Effects on Other Providers

We believe that establishing payment amounts for new DMEPOS items and services will have a positive economic impact on suppliers by making the pricing of new items more easily understood and encourage innovation. The cost cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

This final rule has an indeterminable cost to the Medicare program associated with it due to the unpredictable nature of future new items.

(3) Effects on Medicare Beneficiaries

This final rule has an indeterminable cost to the Medicare beneficiary due to the unpredictable nature of future new items. This rule also has an indeterminable cost to the dual-eligible beneficiary who is enrolled in the Medicare and the Medicaid programs for the same reason as indicated above.

(4) Alternatives Considered

One alternative we considered but did not propose was to continue the process for establishing payment amounts for new items on a sub-regulatory basis. This would have no economic impact on the Medicare program or its beneficiaries.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

(1) Effects on Other Providers

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices will have a negative economic impact on suppliers by lowering fees. The savings cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices will have a positive economic impact on the Medicare Program by lowering fees and achieving savings. The savings cannot be estimated as these new items are not identified.

(3) Effects on Medicare Beneficiaries

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices will have a positive economic impact on Medicare beneficiaries by lowering fees, therefore resulting in lower coinsurance for such items. The savings cannot be estimated as these new items are not identified.

(4) Alternatives Considered

An alternative we considered but did not propose was to continue not adjusting payment amounts for new items based on revised supplier and commercial price lists. This would have resulted, in some cases, in what we

consider to be fee schedule amounts that were too high and a cost to the program and beneficiaries.

5. Conditions of Payment To Be Applied to Certain DMEPOS Items

This rule streamlines the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 23, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 23: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI	
Category	**Transfers**
Annualized Monetized Transfers	$170 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$40 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2022	
Category	**Transfers**
Annualized Monetized Transfers	-$18 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2023	
Category	**Transfers**
Annualized Monetized Transfers	-$18 million
From Whom to Whom	Federal government to ESRD providers

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

D. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $41.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's website at *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf*) (Kidney Dialysis Centers are listed as 621492 with a size standard of $41.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 14. Using the definitions in this ownership category, we consider 502 facilities that are independent and 304 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than $41.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 2.2 percent increase in payments for CY 2020. An independent facility (as defined by ownership type) is estimated to receive a 1.7 percent increase in payments for CY 2020.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $40 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,871 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2023 ESRD QIP, 314 are ESRD small entity facilities. We present these findings in Table 16 (''Estimated Distribution of PY 2023 ESRD QIP Payment Reductions'') and Table 18 (''Impact of QIP Payment Reductions to ESRD Facilities for PY

2023''). We estimate that the payment reductions will average approximately $9,752.58 per facility across the 1,871 facilities receiving a payment reduction, and $9,288.57 for each small entity facility. We also estimate that there are 817 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities will decrease 0.32 percent in CY 2023.

The DMEPOS provisions in this final rule, Establishing Payment Amounts for New DMEPOS Items and Services and Gap-Filling and Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices in section V of this final rule, are not considered to have a significant impact on a number of small suppliers. We note that the fiscal impact of the Conditions of Payment to be applied to Certain DMEPOS Items in section VI of this final rule cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

Therefore, the Secretary has determined that these final rules would not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

We solicited comment on the RFA analysis provided. We received no comments on this section.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 126 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 126 rural hospital-based dialysis facilities will experience an estimated 2.2 percent increase in payments.

Therefore, the Secretary has determined that these final rules would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. These final rules do not include any mandates that would impose spending costs on state, local, or Tribal governments in the aggregate, or by the private sector, of $154 million. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the federal government for providing services that meet federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

F. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed these final rules under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. It has been determined that this is a transfer rule, which imposes no more than de minimis costs. As a result, this rule is not considered a regulatory or deregulatory action under Executive Order 13771.

H. Congressional Review Act

These final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

XI. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and is posted on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov*.

List of Subjects

42 CFR Part 405

Federal health insurance for the aged and disabled, Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologicals, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.36 is amended by revising paragraph (b) to read as follows:

§ 410.36 Medical supplies, appliances, and devices: Scope.

* * * * *

(b) The conditions of payment described in § 410.38(d) also apply to medical supplies, appliances, and devices.

■ 3. Section 410.38 is amended—
■ a. By revising the section heading;
■ b. By revising paragraph (a);
■ c. In paragraph (b) by adding a paragraph heading;
■ d. By revising paragraphs (c), (d), and (e); and
■ e. By removing paragraphs (f) and (g).

The revisions and addition read as follows:

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

(a) *General scope.* Medicare Part B pays for durable medical equipment, including ventilators, oxygen equipment, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) *Institutions that may not qualify as the patient's home.* * * *

(c) *Definitions.* As used in this section:

(1) *Physician* has the same meaning as in section 1861(r)(1) of the Act.

(2) *Treating practitioner* means physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

(3) *DMEPOS supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(4) *Written Order/Prescription* is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.

(5) *Face-to-face encounter* is an in-person or telehealth encounter between the treating practitioner and the beneficiary.

(6) *Power mobility device (PMD)* means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

(7) *Master List of DMEPOS items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, also referred to as* ''*Master List,*'' are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in § 414.234 of this chapter. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

(8) *Required Face-to-Face Encounter and Written Order Prior to Delivery List* is a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery. The list of items is published in the **Federal Register** and posted on the CMS website. The list is effective no less than 60 days following its publication. When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of Payment.* The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription.* All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements.* A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Order Date.

(E) Treating Practitioner Name or National Provider Identifier (NPI).

(F) Treating Practitioner Signature.

(ii) *Timing of the Written Order/Prescription.*

(A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items Requiring a Face-to-Face Encounter.* For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 of this chapter must be met.

(3) *Documentation:* A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements.* CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rulemaking, except those items for which inclusion on the Master List was statutorily imposed.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 4. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 5. Section 413.178 is amended —
■ a. In paragraph (a)(4) by removing the reference ''paragraphs (d)(1)(i) through (v)'' and adding in its place the reference ''paragraphs (e)(1)(i) through (v)'';
■ b. In paragraph (a)(13) by removing the reference to ''paragraph (d)(1)(vi) '' and adding in its place the reference ''paragraph (e)(1)(vi)'';
■ c. By redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively;
■ d. By adding a new paragraph (d);
■ e. In newly redesignated paragraph (e)(2)(i) by removing the reference ''paragraph (d)(1)'' and adding in its place the reference ''paragraph (e)(1)''; and
■ f. In newly redesignated paragraph (f)(2) by removing the cross-reference to ''paragraph (e)(1)'' and adding in its place ''paragraph (f)(1)''.

The revisions and additions read as follows:

§ 413.178 ESRD quality incentive program.

* * * * *

(d) *Data submission requirement.* (1) Except as provided in paragraph (d)(3) and (4) of this section, and for a payment year, facilities must submit to CMS data on each measure specified by CMS under paragraph (c) of this section. Facilities must submit these data in the form, manner, and at a time specified by CMS.

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to the 2023 payment year is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2020 for purposes of calculating the improvement threshold, and the performance period that applies to the 2023 payment year is calendar year 2021. Beginning with the 2024 payment year, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

(3) A facility may request and CMS may grant exceptions to the reporting requirements under paragraph (d)(1) of this section for one or more calendar days, when there are certain extraordinary circumstances beyond the control of the facility.

(4) A facility may request an exception within 90 days of the date that the extraordinary circumstances occurred by submitting the Extraordinary Circumstances Exception request form, which is available on the QualityNet website (*https://www.qualitynet.org/*), to CMS via email to the ESRD QIP mailbox at *ESRDQIP@cms.hhs.gov.* Facilities must provide the following information on the form:

(i) Facility CCN.

(ii) Facility name.

(iii) CEO name and contact information.

(iv) Additional contact name and contact information.

(v) Reason for requesting an exception.

(vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not

limited to photographs, newspaper, and other media articles.

(5) CMS will not consider an exception request unless the facility requesting such exception has complied with the requirements in paragraph (d)(4) of this section.

(6) CMS may grant exceptions to facilities without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) An unresolved issue with a CMS data system affected the ability of a facility to submit data in accordance with paragraph (d)(1) of this section and CMS was unable to provide the facility with an alternative method of data submission.

(7) A facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at *ESRDQIP@cms.hhs.gov.* Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility.

* * * * *

■ 6. Section 413.230 is amended by—
■ a. Revising paragraphs (b) and (c); and
■ b. Adding paragraph (d) and (e).

The revision and additions read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(b) Any outlier payment under § 413.237;

(c) Any training adjustment add-on under § 413.235(c);

(d) Any transitional drug add-on payment adjustment under § 413.234(c); and

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d).

■ 7. Section 413.234, as previously amended on November 14, 2018, is further amended—
■ a. In paragraph (a) by revising the definitions of ''ESRD PPS functional category'' and ''Oral only drug;''
■ b. By revising paragraph (b)(1)(ii);
■ c. By revising paragraph (c) introductory text; and
■ d. By adding paragraph (e).

The revisions and addition read as follows:

§ 413.234 Drug designation process.

(a) * * *

ESRD PPS functional category. A distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

* * * * *

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) * * *

(1) * * *

(ii) Except as provided in paragraph (e) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

* * * * *

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable

time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

* * * * *

(e) *Exclusion criteria for the transitional drug add-on payment adjustment.* A new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in paragraphs (e)(1) through (7) of this section, respectively:

(1) Type 3 NDA—New Dosage Form.

(i) A *Type 3 NDA* is for a new dosage form of an active ingredient that has been approved or marketed in the United States (U.S.) by the same or another applicant but in a different dosage form. The indication for the drug product does not need to be the same as that of the already marketed drug product. Once a new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as a *Type 5 NDA,* as described in paragraph (e)(2) of this section.

(ii) [Reserved]

(2) Type 5 NDA—New Formulation or Other Differences.

(i) A *Type 5 NDA* is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the following:

(A) The product involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and is submitted as an original NDA rather than as a supplement by the applicant of the approved product;

(B) The product is a duplicate of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination), and

(*1*) Requires bioequivalence testing (including bioequivalence studies with clinical endpoints), but is not eligible for submission as a section 505(j) of the FD&C Act application; or

(*2*) Requires safety or effectiveness testing because of novel inactive ingredients; or

(*3*) Requires full safety or effectiveness testing because it is:

(*i*) Subject to exclusivity held by another applicant, or

(*ii*) A product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, or

(*iii*) A crude natural product, or

(*iv*) Ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability (for example, products with different release patterns); or

(*4*) The applicant has a right of reference to the application.

(C) The product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources.

(D) The product is a combination product that differs from a previously marketed combination by the removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one or more of the active ingredients. In the latter case, the NDA would be classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 5 NDA* as described in paragraph (e)(2) of this section.

(E) The product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A *Type 5 NDA,* as described in paragraph (e)(2) of this section, would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

(F) The product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act.

(G) The product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, *Parenteral drug products in plastic containers*).

(ii) [Reserved]

(3) Type 7 NDA—Previously Marketed But Without an Approved NDA.

(i) A *Type 7 NDA* is for a drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the U.S. This classification applies only to the first NDA approved for a drug product containing this (these) active moiety(ies). *Type 7 NDAs* include, but are not limited to:

(A) The first post-1962 application for an active moiety marketed prior to 1938.

(B) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation notice. Regulation at 21 CFR 310.6(b)(1) states that an identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties.

(C) The first application for an IRS drug product first marketed after 1962.

(D) The first application for an active moiety that was first marketed without an NDA after 1962.

(ii) [Reserved]

(4) Type 8 NDA—Prescription to Over-the-Counter (OTC).

(i) A *Type 8 NDA* is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription (OTC switch). A *Type 8 NDA* may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

(ii) If the proposed OTC switch will apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), the applicant should submit a new NDA for the OTC products, which would be classified as a *Type 8 NDA.*

(5) *Combination of Type 3 NDA.* Type 3 NDA, as described in paragraph (e)(1) of this section, in combination with a Type 2 NDA, as described in paragraph

(e)(5)(i) of this section, or in combination with a Type 4 NDA, as described in paragraph (e)(5)(ii) of this section;

(i) Type 2 NDA—New Active Ingredient.

(A) A *Type 2 NDA* is for a drug product that contains a new active ingredient, but not a new molecular entity (NME). A new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. The indication for the drug product does not need to be the same as that of the already marketed product containing the same active moiety.

(B) If the active ingredient is a single enantiomer and a racemic mixture containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a *Type 2 NDA.*

(ii) Type 4 NDA—New Combination.

(A) A *Type 4 NDA* is for a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient. The new product may be a physical or chemical (for example, covalent ester or noncovalent derivative) combination of two or more active moieties.

(B) A new *physical combination* may be two or more active ingredients combined into a single dosage form, or two or more drugs packaged together with combined labeling. When at least one of the active moieties is classified as an NME, the NDA is classified as a combination of a *Type 1 NDA,* as described in paragraph (e)(5)(ii)(B)(*1*) of this section, with a *Type 4 NDA,* as described in paragraph (e)(5)(ii) of this section. When none of the active moieties is an NME, but at least one is a new active ingredient, the NDA is classified as a combination of a *Type 2 NDA,* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA,* as described in paragraph (e)(5)(ii) of this section.

(*1*) Type 1 NDA—New Molecular Entity.

(*i*) A *Type 1 NDA* is for a drug product that contains an NME. An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the FD&C Act or has been previously marketed as a drug in the U.S. A pure enantiomer or a racemic mixture is an NME only when neither has been previously approved or marketed.

(*ii*) An NDA for a drug product containing an active moiety that has been marketed as a drug in the U.S., but never approved in an application submitted under section 505 of the FD&C Act, would be considered a *Type 7 NDA* as described in paragraph (e)(3) of this section, not a *Type 1 NDA.*

(*iii*) An NDA for a drug-drug combination product containing an active moiety that is an NME in combination with another active moiety that had already been approved by FDA would be classified as a new combination containing an NME (that is, *Type 1,4 NDA,* as described in paragraph (e)(5)(ii) of this section). For example, a drug-drug combination can include a fixed-combination drug product or a co-packaged drug product with two or more active moieties.

(*iv*) An active moiety in a radiopharmaceutical (or radioactive drug product) which has not been approved by the FDA or marketed in the U.S. is classified as an NME.

(*v*) In addition, if a change in isotopic form results in an active moiety that has never been approved by the FDA or marketed in the U.S., the active ingredient is classified as an NME.

(C) An NDA for an active ingredient that is a *chemical combination* of two or more previously approved or marketed active moieties that are linked by an ester bond is classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA* as described in paragraph (e)(5)(ii) of this section, if the active moieties have not been previously marketed or approved as a physical combination. If the physical combination has been previously marketed or approved, however, such a product would no longer be considered a *new* combination and the NDA would thus be classified as a *Type 2 NDA,* as described in paragraph (e)(5)(i) of this section.

(6) *Combination of Type 5 NDA.* Type 5 NDA, as described in paragraph (e)(2) of this section, in combination with a *Type 2 NDA,* as described in paragraph (e)(5)(i) of this section.

(7) *Type 9 NDA when the parent NDA is a Type 3, Type 5, Type 7, or a Type 8.* A *Type 9* NDA, as described in paragraph (e)(7)(i) of this section when the parent NDA is a *Type 3* NDA as described in paragraph (e)(1) of this section or a *Type 5* NDA as described in paragraph (e)(2) of this section or *Type 7* NDA as described in paragraph (e)(3) of this section or a *Type 8* NDA as described in paragraph (e)(4) of this section.

(i) Type 9 NDA—New Indication or Claim, Drug Not to be Marketed under Type 9 NDA after Approval.

(A) A *Type 9* NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the ''parent NDA''), and the applicant does not intend to market this drug product under the *Type 9* NDA after approval. Generally, a *Type 9* NDA is submitted as a separate NDA so as to be in compliance with the guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.*

(B) When the *Type 9* NDA is submitted, it will be given the same NDA classification as the pending NDA. When one application is approved, the other will be reclassified as *Type 9* regardless of whether it was the first or second NDA actually submitted. After the approval of a *Type 9* NDA, FDA will ''administratively close'' the *Type 9* NDA and thereafter only accept submissions to the ''parent'' NDA.

(ii) [Reserved]

* * * * *

■ 8. Section 413.236 is added to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis.* This section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(b) *Eligibility criteria.* For dates of service occurring on or after January 1, 2020, CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under § 413.171;

(2) Is new, meaning it is granted marketing authorization by the Food

and Drug Administration (FDA) on or after January 1, 2020;

(3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;

(4) Has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance; and

(6) Is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.* (1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

■ 9. Section 413.237 is amended by—

■ a. Revising paragraph (a)(1)(i) through (iv);

■ b. Redesignating paragraph (a)(1)(v) as paragraph (a)(1)(vi);

■ c. Adding new paragraph (a)(1)(v); and

■ d. Revising newly redesignated paragraph (a)(1)(vi).

The revisions and addition read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and

(v) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

(vi) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 10. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 11. Section 414.110 is added to subpart C to read as follows:

§ 414.110 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General Rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

■ 12. Section 414.112 is added to subpart C to read as follows:

§ 414.112 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process

described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI–U minus current CPI–U) divided by current CPI–U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in § 414.102(c).

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new supplier or commercial prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

■ 13. Section 414.234 is amended —

■ a. In paragraph (a) by adding the definition of ''Required Prior Authorization List'' in alphabetical order;

■ b. By revising the heading of paragraph (b) and revising paragraphs (b)(1), (b)(2), (b)(3)(i) through (b)(3)(iii), (b)(4), and (b)(6);

■ c. By revising paragraphs (c)(1)(i) and (ii);

■ d. By revising paragraphs (d)(1) introductory text and (d)(1)(i);

■ e. By revising paragraph (e)(3) and (4); and

■ f. By adding paragraph (e)(5).

The revisions and addition read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

(a) * * *

Required Prior Authorization List is a list of DMEPOS items selected from the Master List and subject to the requirements of prior authorization as a condition of payment.

* * * * *

(b) *Master List of Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements.*

(1) Master List Inclusion Criteria are as follows:

(i) Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of $500 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of $50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI–U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a 12-month period that are:

(A) Identified as having a high rate of potential fraud or unnecessary utilization in an Office of Inspector General (OIG) or Government Accountability Office (GAO) report that is national in scope and published in 2015 or later, or

(B) Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(ii) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

(A) Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

(B) Exceeding a 30 percent increase in payment, or

(iii) Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

(2) The Master List is self-updating at a minimum annually, and is published in the **Federal Register**.

(3) * * *

(i) OIG reports published after 2020.

(ii) GAO reports published after 2020.

(iii) Listed in the CERT Medicare FFS Supplemental Improper Payment Data report(s) published after 2020 as having a high improper payment rate.

(4) Items are removed from the Master List after 10 years from the date the item was added to the Master List, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

* * * * *

(6) An item is removed from the list if the cost drops below the payment threshold criteria set forth in paragraph (b)(1)(i) of this section.

* * * * *

(c) * * *

(1) * * *

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List. CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in

official agency reports, or other analysis and may implement prior authorization nationally or locally.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process.

* * * * *

(d) * * *

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including those outlined in § 410.38 and all of the following:

(i) Written order/prescription.

* * * * *

(e) * * *

(3) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(4) If the requester receives a non-affirmation decision, the requester may resubmit a prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(5) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function. If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

* * * * *

■ 14. Section 414.236 is added to subpart D to read as follows:

§ 414.236 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

■ 15. Section 414.238 is added to subpart D to read as follows:

§ 414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI–U minus current CPI–U) divided by current CPI–U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME, section 1834(h)(4) of the Act for prosthetic devices, prosthetics, orthotics, and therapeutic shoes and inserts, and section 1834(i)(1)(B) of the Act for surgical dressings.

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

■ 16. Section 414.422 is amended by revising paragraph (d) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(d) *Change of ownership (CHOW).* (1) CMS may transfer a contract to a successor entity that merges with, or acquires, a contract supplier if the successor entity—

(i) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not needed to make a financial determination. This documentation must be submitted prior to the effective date of the CHOW; and

(iii) Submits to CMS a signed novation agreement acceptable to CMS stating that it assumes all obligations under the contract. This documentation must be submitted no later than 10 days after the effective date of the CHOW.

(2) Except as specified in paragraph (d)(3) of this section, CMS may transfer the entire contract, including all product categories and competitive bidding areas, to a successor entity.

(3) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company (for example, a subsidiary) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a successor entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the successor entity that meets all competitive bidding requirements; that is, financial, accreditation, and licensure;

(ii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iii) All requirements of paragraph (d)(1) of this section are met;

(iv) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(v) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

* * * * *

■ 17. Section 414.423 is amended by revising paragraph (f)(2) to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

* * * * *

(f) * * *

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

* * * * *

Dated: October 24, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 28, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Updated Life Expectancy and Distribution Period Tables Used for Purposes of Determining Minimum Required Distributions; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–132210–18]

RIN 1545–BP11

Updated Life Expectancy and Distribution Period Tables Used for Purposes of Determining Minimum Required Distributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of public hearing.

SUMMARY: This document sets forth proposed regulations providing guidance relating to the life expectancy and distribution period tables that are used to calculate required minimum distributions from qualified retirement plans, individual retirement accounts and annuities, and certain other tax-favored employer-provided retirement arrangements. These regulations affect participants, beneficiaries, and plan administrators of these qualified retirement plans and other tax-favored employer-provided retirement arrangements, as well as owners, beneficiaries, trustees and custodians of individual retirement accounts and annuities. This document also provides a notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by January 7, 2020. Outlines of topics to be discussed at the public hearing scheduled for January 23, 2020, must be received by January 7, 2020.

ADDRESSES: Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–132210–18) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment received to its public docket, whether submitted electronically or in hard copy. Send hard copy submissions to: CC:PA:LPD:PR (REG–132210–18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–132210–18), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Arslan Malik or Linda S.F. Marshall, (202) 317–6700; concerning submissions of comments and requests to speak at the public hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document includes proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 401(a)(9) of the Internal Revenue Code (Code) regarding the requirement to take required minimum distributions from qualified trusts. These proposed regulations also apply with respect to the corresponding requirements for individual retirement accounts and annuities described in section 408(a) and (b), and eligible deferred compensation plans under section 457, as well as section 403(a) and 403(b) annuity contracts, custodial accounts, and retirement income accounts.

Section 401(a)(9) provides rules regarding minimum required distributions from qualified retirement plans. The purpose of section 401(a)(9) is to ensure that the favorable tax treatment afforded a qualified plan is used primarily to provide retirement income to a participant and a designated beneficiary, rather than to increase the estate of a participant. Accordingly, section 401(a)(9) provides that a qualified plan must commence benefits to an employee no later than a specified age (or within a specified number of years after the employee's death) and, under the regulations, once benefits commence, the pattern of payment must meet certain standards to ensure that distributions are not unduly deferred.

Section 401(a)(9)(A) provides rules for distributions during the life of the employee. Section 401(a)(9)(A)(ii) provides that the entire interest of an employee in a qualified plan must be distributed, beginning not later than the employee's required beginning date, in accordance with regulations, over the life of the employee or over the lives of the employee and a designated beneficiary (or over a period not extending beyond the life expectancy of the employee and a designated beneficiary).

Section 401(a)(9)(B) provides rules for distributions that are made after the death of the employee. Section 401(a)(9)(B)(i) provides that, if the employee dies after distributions have begun, the employee's interest must be distributed at least as rapidly as under the method used by the employee. Section 401(a)(9)(B)(ii) and (iii) provide that, if the employee dies before distributions have begun, the employee's interest must be either (1) Distributed (in accordance with regulations) over the life or life expectancy of the designated beneficiary with the distributions beginning no later than 1 year after the date of the employee's death, or (2) distributed within 5 years after the death of the employee. However, under section 401(a)(9)(B)(iv), a surviving spouse may wait until the date the employee would have attained age 70½ to begin receiving required minimum distributions.

Section 401(a)(9)(C) defines the term *required beginning date* for employees (other than 5-percent owners and IRA owners) as April 1 of the calendar year following the later of the calendar year in which the employee attains age 70½ or the calendar year in which the employee retires. For 5-percent owners and IRA owners, the required beginning date is April 1 of the calendar year following the calendar year in which the employee attains age 70½, even if the employee has not retired.

Section 401(a)(9)(D) provides that, except in the case of a life annuity, the life expectancy of an employee and the employee's spouse that is used to determine the period over which payments must be made may be re-determined, but not more frequently than annually.

Section 401(a)(9)(E) provides that the term *designated beneficiary* means any individual designated as a beneficiary by the employee.

Section 401(a)(9)(G) provides that any distribution required to satisfy the incidental death benefit requirement of section 401(a)[1] is a required minimum distribution.

Under sections 403(b)(10), 408(a)(6),[2] and 457(d)(2), requirements similar to the requirements of section 401(a)(9) apply to a number of types of retirement arrangements other than qualified plans. Pursuant to sections 403(a)(1) and 404(a)(2), qualified annuity plans must also comply with the requirements of section 401(a)(9).

Comprehensive rules regarding the application of section 401(a)(9) are set

[1] The incidental death benefit requirement, which is set forth in § 1.401–1(b)(1), provides that although a qualified pension or profit-sharing plan may provide for incidental death (or life insurance) benefits, such a plan must be established and maintained primarily for the purpose of providing retirement benefits or deferred compensation.

[2] However, pursuant to section 408A(a) and (c)(5), the minimum required distribution rules of section 401(a)(9) apply to a Roth IRA only after the death of the IRA owner.

forth in §§ 1.401(a)(9)–1 through 8. In the case of a defined contribution plan, § 1.401(a)(9)–5 provides generally that an individual's required minimum distribution for a distribution calendar year is determined by dividing the individual's account balance determined under § 1.401(a)(9)–5, Q&A–3, by the applicable distribution period. Under § 1.401(a)(9)–5, Q&A–1(b), a distribution calendar year is a calendar year for which a minimum distribution is required. For example, if a 5-percent owner participating in a qualified plan attained age 70½ during August of 2018 (so that the required beginning date was April 1, 2019), then the first distribution calendar year was 2018, and the required minimum distribution for that year was based on the applicable distribution period for a 70-year-old individual for 2018 (even though it could have been paid at any time from January 1, 2018 through April 1, 2019).

Pursuant to § 1.401(a)(9)–5, Q&A–4(a), for required minimum distributions during the employee's lifetime (including the year in which the employee dies), the applicable distribution period for an employee is the distribution period for the employee's age under the Uniform Lifetime Table (which is equal to the joint and last survivor life expectancy for the employee and a hypothetical beneficiary 10 years younger). However, pursuant to § 1.401(a)(9)–5, Q&A–4(b), if an employee's sole beneficiary is the employee's surviving spouse and the spouse is more than 10 years younger than the employee, then the applicable distribution period is the joint and last survivor life expectancy of the employee and spouse under the Joint and Last Survivor Table (which is longer than the distribution period that would apply for the employee under the Uniform Lifetime Table).

Pursuant to § 1.401(a)(9)–5, Q&A–5, for distribution calendar years after the calendar year of the employee's death, the applicable distribution period generally is the remaining life expectancy of the designated beneficiary, subject to certain exceptions. Two of these exceptions, which apply if the employee dies after the required beginning date, substitute the employee's remaining life expectancy for the beneficiary's remaining life expectancy. These two exceptions apply to an employee who does not have a designated beneficiary or is younger than the designated beneficiary.[3] Section 1.401(a)(9)–5, Q&A–5(c)(1) provides that the remaining life expectancy of the designated beneficiary is calculated as the life expectancy under the Single Life Table for the designated beneficiary's age in the calendar year following the calendar year of the employee's death, reduced by 1 for each subsequent year. However, if one of the two exceptions applies (so that the relevant life expectancy is the remaining life expectancy of the employee), then, pursuant to § 1.401(a)(9)–5, Q&A–5(c)(3), the remaining life expectancy of the employee is calculated as the life expectancy under the Single Life Table for the employee's age in the calendar year of the employee's death, reduced by 1 for each subsequent year.

A special rule applies to determine the designated beneficiary's remaining life expectancy if the employee's surviving spouse is the employee's sole beneficiary. In that case, pursuant to § 1.401(a)(9)–5, Q&A–5(c)(2), the designated beneficiary's remaining life expectancy is recalculated each calendar year as the life expectancy under the Single Life Table for the designated beneficiary's age in that year. For calendar years after the year of the spouse's death, the distribution period that applies for the spouse's beneficiary is the spouse's remaining life expectancy from the Single Life Table for the spouse's age for the calendar year of the spouse's death, reduced by 1 for each subsequent year.

Consistent with the policy of section 401(a)(9) to limit deferral of retirement income, § 1.401(a)(9)–6, Q&A–1(a) provides that, except as otherwise provided in § 1.401(a)(9)–6, payments from a defined benefit plan must be non-increasing in order to satisfy section 401(a)(9).[4] Section 1.401(a)(9)–6, Q&A–14(c) provides that, in the case of annuity payments paid from an annuity contract purchased from an insurance company, certain types of increasing payments will not cause an annuity payment stream to fail to satisfy this non-increasing payment requirement. These exceptions apply only if the total future expected payments under the annuity contract (determined in accordance with § 1.401(a)(9)–6, Q&A–14(e)(3)) exceed the total value being annuitized (determined in accordance with § 1.401(a)(9)–6, Q&A–14(e)(1)).

Section 1.401(a)(9)–9 provides life expectancy and distribution period tables that are used to apply the rules of § 1.401(a)(9)–5 and to make the calculations in § 1.401(a)(9)–6, Q&A–14. Section 1.401(a)(9)–9 was issued in 2002 (67 FR 18988), and the tables in that section were developed using mortality rates for 2003. These mortality rates were derived by applying mortality improvement through 2003 to the mortality rates from the Annuity 2000 Basic Table (which was the most recent individual annuity mortality table available in 2002).[5] The rates of mortality improvement used for this purpose were the ones that were used in developing that mortality table. The resulting separate mortality rates for males and females were blended using a fixed 50 percent male/50 percent female blend.

Section 72(t) imposes an additional income tax on early distributions from qualified retirement plans (including plans qualified under section 401(a) or section 403(a), annuity contracts and other arrangements described in section 403(b), and individual retirement arrangements described in section 408(a) or section 408(b)). However, section 72(t)(2)(A)(iv) provides an exception for a series of substantially equal periodic payments made for the life (or life expectancy) of the employee or the joint lives (or joint life expectancies) of the employee and the designated beneficiary. Revenue Ruling 2002–62, 2002–2 C.B. 710, provides that the life expectancy tables set forth in § 1.401(a)(9)–9 may be used for purposes of determining payments that satisfy the exception under section 72(t)(2)(A)(iv). Rev. Rul. 2002–62 also provides a fixed annuitization method of determining payments that satisfy this exception. Under the fixed annuitization method, the annual payment for each year (which is determined only for the first year and not reset for subsequent years) is determined by dividing the account balance by an annuity factor that is the present value of an annuity of $1 per year beginning at the taxpayer's age and continuing for the life of the taxpayer (or the joint lives of the taxpayer and his or her beneficiary). The annuity factor is derived using the mortality table used to develop the life expectancy tables set forth in § 1.401(a)(9)–9.

Executive Order 13847, 83 FR 45321, which was signed on August 31, 2018, directs the Secretary of the Treasury to examine the life expectancy and distribution period tables in the regulations on required minimum

[3] Another exception applies if the employee dies before the required beginning date and has no designated beneficiary. In that case, the employee's entire interest must be distributed by the end of the calendar year that includes the fifth anniversary of the date of the employee's death.

[4] Pursuant to § 1.401(a)(9)–8, Q&A–2(a)(3), the rules of § 1.401(a)(9)–6 also apply to an annuity contract purchased under a defined contribution plan.

[5] The Annuity 2000 Basic Table was developed by projecting mortality rates from the 1983 Individual Annuity Mortality Basic Table.

distributions from retirement plans and determine whether they should be updated to reflect current mortality data and whether such updates should be made annually or on another periodic basis. The purpose of any such updates would be to increase the effectiveness of tax-favored retirement programs by allowing retirees to retain sufficient retirement savings in these programs for their later years.

Explanation of Provisions

I. Overview

In accordance with Executive Order 13847, the Department of the Treasury (Treasury Department) and the IRS have examined the life expectancy and distribution period tables in § 1.401(a)(9)–9, and have reviewed currently available mortality data. As a result of this review, the Treasury Department and the IRS have determined that those tables should be updated to reflect current life expectancies. Accordingly, these proposed regulations would update those tables.

The life expectancy tables and applicable distribution period tables in the proposed regulations reflect longer life expectancies than the tables in the existing regulations. For example, a 70-year old IRA owner who uses the Uniform Lifetime Table to calculate required minimum distributions must use a life expectancy of 27.4 years under the existing regulations. Using the Uniform Lifetime Table set forth in the proposed regulations, this IRA owner would use a life expectancy of 29.1 years to calculate required minimum distributions. As another example, under the existing regulations, a 75-year old surviving spouse who is the employee's sole beneficiary and uses the Single Life Table to compute required minimum distributions must use a life expectancy of 13.4 years. Under the proposed regulations, the spouse would use a life expectancy of 14.8 years. The effect of these changes is to reduce required minimum distributions, which will allow participants to retain larger amounts in their retirement plans to account for the possibility they may live longer.

II. Updated Life Expectancy and Distribution Period Tables

The life expectancy and distribution period tables in the proposed regulations have been developed based on mortality rates for 2021. These mortality rates were derived by applying mortality improvement through 2021 to the mortality rates from the experience tables used to develop the 2012 Individual Annuity Mortality tables (which are the most recent individual annuity mortality tables).[6] The separate mortality rates for males and females in these experience tables, which were based on the Payout Annuity Mortality Experience Study (which covered the period 2000 to 2004), have been projected from the central year of 2002 using the respective mortality improvement rates from the Mortality Improvement Scale MP–2018 for males and females.[7] The mortality table in the proposed regulations was developed by blending the resulting separate mortality rates for males and females using a fixed 50 percent male/50 percent female blend.

The Single Life Table in the proposed regulations sets forth life expectancies for each age, with the life expectancy for an age calculated as the sum of the probabilities of an individual at that age surviving to each future year. The resulting life expectancy is then increased by 11/24[8] to approximate the effect of monthly payments, and is subject to a floor of 1.0.

The Uniform Lifetime Table in the proposed regulations sets forth joint and last survivor life expectancies for each age beginning with age 70, based on a hypothetical beneficiary. Pursuant to § 1.401(a)(9)–5, Q&A–4(a), the Uniform Lifetime Table is used for determining the distribution period for lifetime distributions to an employee in situations in which the employee's surviving spouse either is not the sole designated beneficiary or is the sole designated beneficiary but is not more than 10 years younger than the employee. As under the existing regulations, the joint and last survivor life expectancy of an employee is taken from the Joint and Last Survivor Table using a hypothetical beneficiary who is assumed to be 10 years younger than the employee.

The Joint and Last Survivor Table sets forth joint and last survivor life expectancies of an employee and the employee's beneficiary for each combination of ages of those individuals. The joint and last survivor life expectancy for an employee and a beneficiary at a combination of ages is calculated as the sum of the probabilities of the employee surviving to each future year, plus the sum of the probabilities of the beneficiary surviving to each future year, minus the sum of the probabilities of both the employee and beneficiary surviving to each future year. The resulting joint and last survivor life expectancy is then increased by 11/24 to approximate the effect of monthly payments, and is subject to a floor of 1.0.

The life expectancy tables in the current regulations are used in several examples in § 1.401(a)(9)–6, Q&A–14(f) that illustrate the availability of the exception described in § 1.401(a)(9)–6, Q&A–14(c) (regarding certain increasing payments under insurance company annuity contracts). These proposed regulations do not include revisions to these examples to reflect the life expectancy tables in the proposed regulations.

III. Effective/Applicability Date

The life expectancy tables and Uniform Lifetime Table under these proposed regulations would apply for distribution calendar years beginning on or after January 1, 2021. Thus, for example, for an individual who attains age 70½ during 2020 (so that the minimum required distribution for the distribution calendar year 2020 is due April 1, 2021), the final regulations would not apply to the minimum required distribution for the individual's 2020 distribution calendar year (which is due April 1, 2021), but would apply to the minimum required distribution for the individual's 2021 distribution calendar year (which is due December 31, 2021).

These proposed regulations include a transition rule that applies if an employee died before January 1, 2021, and, under the rules of § 1.401(a)(9)–5, Q&A–5, the distribution period that applies for calendar years following the calendar year of the employee's death is equal to a single life expectancy calculated as of the calendar year of the employee's death (or if applicable, the year after the employee's death), reduced by 1 for each subsequent year. Under this transition rule, the initial life expectancy used to determine the distribution period is reset by using the new Single Life Table for the age of the relevant individual in the calendar year for which life expectancy was set under § 1.401(a)(9)–5, Q&A 5(c). For distribution calendar years beginning on or after January 1, 2021, the distribution period is determined by reducing that initial life expectancy by 1 for each year subsequent to the year for which it was initially set.

[6] The experience tables and the 2012 Individual Annuity Mortality tables can be found at *https://www.actuary.org/sites/default/files/files/publications/Payout_Annuity_Report_09-28-11.pdf*.

[7] The Mortality Improvement Scale MP–2018 can be found at *https://www.soa.org/experience-studies/2018/mortality-improvement-scale-mp-2018/*.

[8] Assuming an equal distribution of deaths throughout the year, if a retiree is scheduled to receive monthly payments on the last day of each month then, in the year of death, on average, the retiree would receive 11/24th of a full year's worth of payments.

This transition rule applies in three situations: (1) The employee died before the required beginning date with a non-spousal designated beneficiary (so that the applicable distribution period is determined based on the remaining life expectancy of the designated beneficiary for the calendar year following the calendar year of the employee's death); (2) the employee died after the required beginning date without a designated beneficiary (so that the applicable distribution period is determined based on the remaining life expectancy of the employee for the year of the employee's death); and (3) the employee, who is younger than the designated beneficiary, died after the required beginning date (so that the applicable distribution period is determined based on the remaining life expectancy of the employee for the year of the employee's death).

The proposed regulations illustrate the application of this transition rule with an example involving an employee who died at age 80 in 2018 with a designated beneficiary (who was not the employee's spouse) who was age 75 in the year of the employee's death. For 2019, the distribution period that applies for the beneficiary is 12.7 years (the period applicable for a 76 year old under the Single Life Table in current § 1.401(a)(9)–9), and for 2020, it is 11.7 years (the original distribution period, reduced by 1 year). For 2021, taking into account the life expectancy tables under the proposed regulations and applying the transition rule, the applicable distribution period would be 12.0 years (the 14.0 year life expectancy for a 76 year old under the Single Life Table in the proposed regulations, reduced by 2 years).

A similar transition rule applies if an employee's sole beneficiary is the employee's surviving spouse and the spouse died before January 1, 2021. Under the rules of § 1.401(a)(9)–5, Q&A–5(c)(2), the distribution period that applies for the spouse's beneficiary is equal to the single life expectancy for the spouse calculated for the calendar year of the spouse's death, reduced by 1 for each subsequent year. Under the transition rule, the initial life expectancy used to determine the distribution period is reset by using the new Single Life Table for the age of the spouse in the calendar year of the spouse's death. For distribution calendar years beginning on or after January 1, 2021, the distribution period is determined by reducing that initial life expectancy by 1 for each year subsequent to the year for which it was initially set.

These transition rules, under which there is a one-time reset for the relevant life expectancy using the Single Life Table under the proposed regulations, are designed to recognize that the general population has longer life expectancies than the life expectancies set forth in the 2002 regulations. However, because the reset life expectancy is based on the age for which life expectancy was originally determined (rather than the relevant individual's current age), it is consistent with Congressional intent to limit recalculation of life expectancy to the employee and the employee's spouse.

IV. Applicability to Revenue Ruling 2002–62

After final regulations that provide updated life expectancy and distribution period tables under section 401(a)(9) are issued, if a taxpayer commenced receiving substantially equal periodic payments before January 1, 2021, using the required minimum distribution method described in section 2.01(a) of Rev. Rul. 2002–62, then the application of the final regulations will not be treated as a modification to a series of substantially equal periodic payments as described in section 72(t)(4)(A)(ii). In addition, if a taxpayer commences receiving substantially equal periodic payments on or after January 1, 2021, and uses either the fixed amortization method described in section 2.01(b) of Rev. Rul. 2002–62 or the fixed annuitization method described in section 2.01(c) of Rev. Rul. 2002–62, then the method should be applied by applying the corresponding life expectancy, distribution period, and mortality tables in the final regulations in lieu of the tables in formerly applicable § 1.401(a)(9)–9 that are referenced in Rev. Rul. 2002–62.

Special Analyses

I. Regulatory Impact Analysis

Executive Orders 13771, 13563, and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Executive Order 13771 designation for any final rule resulting from the proposed regulation will be informed by comments received. The preliminary Executive Order 13771 designation for this proposed rule is deregulatory.

The proposed regulations have been designated by the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA, April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. OIRA has determined that the proposed rulemaking is significant and subject to review under Executive Order 12866 and section 1(b) of the Memorandum of Agreement. Accordingly, the proposed regulations have been reviewed by OMB.

1. Introduction and Need for Regulation

As stated earlier in the preamble to the proposed regulations, in accordance with Executive Order 13847, the Treasury Department and the IRS have examined the life expectancy and distribution period tables in § 1.401(a)(9)–9 and have reviewed currently available mortality data. As a result of this review, the Treasury Department and the IRS determined that those tables should be updated to reflect current life expectancies.

The life expectancy tables and applicable distribution period tables in the proposed regulations reflect longer life expectancies than the tables in the existing regulations. The effect of these changes is to reduce annual required minimum distributions (RMDs) from qualified defined contribution plans, IRAs, and certain other tax-favored retirement plans (referred to as affected retirement plans). The purpose of such updates is to increase the effectiveness of these tax-favored retirement programs by allowing retirees to retain more retirement savings in these programs for their later years.

Pursuant to section 6(a)(3)(B) of Executive Order 12866, the following qualitative analysis provides further details regarding the anticipated impacts of the proposed regulations. After briefly describing the proposed regulations in Part 2, the baseline used for the analysis is described in Part 3. Part 4 describes the entities and individuals affected by the proposed regulations. Part 5 provides a qualitative assessment of the potential economic effects, including benefits and costs, of the proposed regulations compared to the baseline.

2. The Proposed Regulations

The RMD rules require an individual to withdraw assets from an affected retirement plan as generally taxable distributions over the life expectancy of the individual (or the individual and spouse).[9] Balances remaining at the death of the individual that are paid to a spouse as designated beneficiary must generally be withdrawn over the life expectancy of the spouse.[10] The purpose of the RMD rules is to ensure that the favorable tax treatment afforded a qualified plan is used primarily to provide retirement income to a participant and designated beneficiary, while mitigating the cost to the government of deferred taxation on savings in qualified retirement plans.

The life expectancy tables and applicable distribution period tables in the proposed regulations reflect longer life expectancies than the tables in the existing regulations that are generally between one and two years longer than under the existing regulations. This will give individuals with affected retirement plans the option to withdraw slightly smaller amounts from their plans each year, giving individuals and beneficiaries the option to leave amounts in tax-favored retirement accounts for a slightly longer period of time, to account for the possibility that they may live longer.

3. Baseline

The Treasury Department and the IRS have assessed the benefits and costs of these proposed regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these proposed regulations.

4. Affected Entities and Individuals

The proposed regulations affect individuals who withdraw exactly the RMD amount from their affected retirement plan but who would prefer to withdraw less in the absence of the minimum distribution requirements. Individuals who withdraw more than the current RMD are not bound by the current rules and therefore are not expected to reduce withdrawals as a result of the proposed regulations. Using confidential tax return data, the Treasury Department estimates roughly 4.6 million individuals, or 20.5% of all individuals required to take RMDs from an affected retirement plan, will make withdrawals at the minimum required level in 2021, and might reduce withdrawals as a result of the rule.

In addition, Individual Retirement Account (IRA) providers would have to change the administration of their IRAs to reflect the new life expectancy tables. The Treasury Department does not have an estimate of the number of such entities. Additionally, employer plans that do not require benefits to be paid out as a lump sum would have to change the administration of their plans to reflect the new life expectancy tables. The Treasury Department expects that this would include most large plans, which typically do not require benefits to be paid out in a lump sum and thus would be affected by the proposed regulations. The latest available data, the Private Pension Bulletin produced by the Department of Labor, indicate there were 81,469 large qualified pension plans (defined as plans with more than 100 participants) in 2016.[11]

5. Economic Effects

a. Labor Supply Effect

The proposed rule produces a positive wealth effect, as lower levels of RMDs lead to larger amounts of assets earning tax-deferred returns. While this might plausibly lead to a reduction in labor supply, this effect is likely to be small for the following reasons.

First, the proposed regulations would lead to a small decrease in the portion of assets in affected retirement plans that must be withdrawn as an RMD for a 70-year old retiree. Under the current regulations, if a 70-year old retiree had $250,000 in his or her affected retirement plan, the individual is required at age 70 to withdraw $9,124, equal to 3.65% of plan assets. Under the proposed regulations, the individual would be required to withdraw $8,591, equal to 3.44% of plan assets, a decrease of $533 or 0.21% of plan assets. Under the current regulations, a 90-year old retiree with $250,000 in his or her affected retirement plan would be required at age 90 to withdraw $21,930, equal to 8.77% of plan assets. Under the proposed regulations, the individual would be required to withdraw $20,661, equal to 8.26% of plan assets, a decrease of $1,269 or 0.51% of plan assets.

Second, the proposed regulations are expected to affect the labor supply decisions only of individuals who are making withdrawals at or very close to the RMD level. Individuals making withdrawals from affected retirement plans exceeding the current RMD are not bound by the current minimum and are therefore not affected by relaxing the minimum by a small amount. Hence, their labor supply decisions are unlikely to change based on the proposed regulations. Thus, the proposed regulations would likely affect only a very small portion of high income individuals working into their late 60s and early 70s.

The small impact of the proposed regulations is illustrated by an example. Assume the following facts. The individual is unmarried and has $250,000 in his or her IRA and $0 in a taxable account. The individual turns age 70 on January 1 and because the individual turns 70½ in the year must begin taking RMDs. The RMD amount is determined as of January 1, but is withdrawn on December 31 of the year in question. Tax is paid immediately upon the withdrawal of the RMD. Because the individual who is bound by the RMD rules has revealed a preference to continue to save the funds rather than consume them, the amount remaining after the tax has been paid on the distribution is placed into a taxable investment account on January 1 of the following year (the day after the RMD is made). Assets held in the IRA and the taxable account earn a 3% rate of return once the individual turns age 70. The RMDs and the returns in the taxable account are taxed at a marginal rate of 22%.

Under the mortality rates in the proposed regulations, an individual who is 70 is expected to live until approximately age 90. We examine the total assets, *i.e.,* the sum of the assets in the IRA and in the taxable account, that the taxpayer would have at age 90 if the individual only takes RMDs each year. Under the current regulations, the individual's total assets at age 90 would be $371,004. Under the proposed regulations, the individual's total assets at age 90 would be $374,461. This $3,457 (less than 1%) increase in total assets at age 90 is unlikely to allow or incentivize the individual to retire earlier than he or she otherwise would.

The proposed regulations could in theory lead to an increase in labor supply. The argument is that because the value of contributing to a retirement fund has increased, the return to working longer has increased. Another example illustrates that the additional return to working is small and very unlikely to induce an increase in labor supply.

Assume the following facts. The individual is unmarried and is age 69.

[9] This requirement to take distributions during the individual's lifetime does not apply to a Roth IRA described in section 408A.

[10] Balances payable to other designated beneficiaries must generally be withdrawn according to the beneficiary's life expectancy (fixed as of the year of death). Different rules apply if the individual dies prior to the required beginning date for RMDs.

[11] *https://www.dol.gov/sites/default/files/ebsa/researchers/statistics/retirement-bulletins/private-pension-plan-bulletin-historical-tables-and-graphs.pdf.*

The individual chooses whether to work an additional year or to retire. If the individual works an additional year, the individual's income is sufficiently large so that the individual would choose to contribute the maximum amount to an IRA ($7,000 in 2019). If the individual retires, the individual does not contribute to an IRA. That is, if the individual retires at age 69, the individual will have $250,000 of assets in his or her IRA and $0 in a taxable account on January 1 in the year the individual turns age 70. If the individual retires at age 70, the individual will have $257,000 of assets in his or her IRA and $0 in a taxable account on January 1 in the year the individual turns age 70.

As in the previous example, the individual has RMDs beginning at age 70½. The RMD amount is determined on January 1 but is withdrawn on December 31 of the year in question. Tax is paid immediately upon the withdrawal of the RMD amount. The amount remaining after the tax has been paid on the distribution is placed on January 1 of the following year, *i.e.,* the day after the RMD was made, into a taxable investment account. Assets held in the IRA and the taxable account earn a 3% rate of return once the individual turns age 70. The RMDs and the returns in the taxable account are taxed at a marginal tax rate of 22%.

We again examine the total assets, *i.e.,* the sum of the assets in the IRA and in the taxable account that the individual would have at age 90. If the individual waits to retire at age 70, under the current RMD rules, the individual's total assets at age 90 would be $10,388 more than if the taxpayer retired at age 69. Under the proposed rulemaking, if the individual waits to retire at age 70, the individual's total assets at age 90 would be $10,485 more than if the individual retired at age 69.

The proposed rulemaking, therefore, increases the difference in total assets at age 90 by $97. Even if the individual contributed the $25,000 maximum to a 401(k) plan—$19,000 plus $6,000 in catch-up contributions in 2019—the proposed rulemaking would increase the difference in total assets at age 90 by only $346. These amounts are likely much too small to affect the individual's decision about whether to retire at age 69 or wait to retire at age 70.

Under the standard assumption that leisure is a normal good, *i.e.,* time spent not working increases as income and wealth increase, the increase in potential retirement income generated by the proposed rulemaking could lead some individuals to work less. However, given the magnitude of the change as suggested in the preceding example, this behavior is unlikely.

b. Increased Fees

Under the proposed regulations, more assets will be left in affected retirement plans. Using confidential tax data, the Treasury Department estimates that in 2021, the proposed regulations would lead to an $8.1 billion reduction in distributions from affected retirement plans. A joint study by Brightscope and the Investment Company Institute indicates that ''all-in'' fees for large plans, which are the ones most likely not to require distributions to be taken as a lump sum, are typically below 1%.[12] Thus, reduced withdrawals could lead to an increase in fees of about $81 million earned by providers of services to affected retirement plans in 2021. However, in the absence of the proposed regulations, individuals who prefer to make smaller withdrawals would likely transfer these funds into taxable investment accounts, which carry their own fees. As a result, the net additional fees earned by the investment industry as a result of the proposed regulations are expected to be much less than $81 million.

c. Administrative Costs

Under the proposed regulations, all IRA providers and administrators of employer-sponsored retirement plans that allow non-lump sum distributions will need to update their life expectancy and distribution period tables and communicate the changes in their RMDs to their plan participants. However, most employers use purchased software of third-party service providers that provide plan administrative services for many employers. This creates economies of scale and reduces the total cost of the required update. The total cost will then be spread over many employers, such that the cost to each employer is expected to be very low. The Treasury Department and the IRS do not have sufficient data to determine the increased administrative costs of the proposed regulations for an individual IRA provider, plan administrator who uses in-house software, plan service provider or software developer, and invite comments on the cost of implementing the life expectancy and distribution period table in the proposed regulations for these entities. The Treasury Department and the IRS also invite comments on the number of such entities who would have to implement changes to software in order to implement the life expectancy and distribution period table in the proposed regulations.

II. Regulatory Flexibility Act

It is hereby certified pursuant to the Regulatory Flexibility Act *5 U.S.C., chapter 6) that these proposed regulations will not have a significant economic impact on a substantial number of small entities. These proposed regulations will apply to all employers that sponsor defined contribution plans regardless of size. Although data are not available to estimate the number of small entitles affected, the proposed rule may affect a substantial number. As stated above, this rule updates life expectancies that are required to be used by statute.

Although the proposed rule may affect a substantial number of small entities, the economic impact of the proposed regulations is not likely to be significant. Small businesses generally comply with the minimum required distribution rules using either third-party administrators or software, creating economies of scale that mitigate the cost of updating life expectancy tables. Such software is updated periodically irrespective of a change in life expectancies used to determine minimum required distributions. The portion of the cost of a periodic update that is attributable to the implementation of the life expectancy and distribution period tables in the proposed regulations will be spread over the client base of a service provider that uses software developed in-house, and over the group of purchasers of generally-available plan administration software. Because, in either case, the cost of changing software to implement the updated life expectancies is spread over a large group of businesses that maintain retirement plans, it is estimated that the incremental cost for each affected small businesses as a result of the use of updated life expectancies is not significant.

Notwithstanding this certification, Treasury and the IRS invite comments about the impact that the proposed rule would have on small entities. Pursuant to section 7805(f) of the Code, this

[12] See ''The Brightscope/ICI Defined Contribution Plan Profile: A Close Look at 401(k) Plans'' (December 2014) at *https://www.ici.org/pdf/ppr_14_dcplan_profile_401k.pdf.* This study points to page 7 of ''Inside the Structure of Defined Contribution/401(k) Plan Fees, 2013: A study assessing the mechanics of the 'all-in' fee'' (August 2014) at *https://www.ici.org/pdf/rpt_14_dc_401k_fee_study.pdf,* for a definition of the 'all-in fee.' This definition of 'all-in fee' ''. . . includes all administrative or recordkeeping fees as well as investment fees (*i.e.,* the investment option's total expense ratio) whether they are assessed at the plan, employer or participant level. The 'all-in' fee excludes those recordkeeping and administrative activity fees that only apply to particular participants who engage in the activity (*e.g.,* self-directed brokerage, managed accounts, loans, QDROs and distributions).''

notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small entities.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the Treasury Department and the IRS as prescribed in this preamble in the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of these proposed regulations, including:

- How often the life expectancy and distribution period tables in these regulations should be updated.
- The extent of the administrative burden involved in implementing any such updates.
- Whether guidance is needed so that a participant whose plan administrator or trustee fails to implement the final regulations in a timely fashion may take required minimum distributions (or roll over distributions in excess of the required minimum distribution) in a manner that takes into account the final regulations.

All comments will be available for public inspection and copying at *www.regulations.gov* or upon request.

A public hearing on these proposed regulations has been scheduled for January 23, 2020, beginning at 10 a.m. in the IRS Auditorium, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written or electronic comments by January 7, 2020, and an outline of topics to be discussed and the amount of time to be devoted to each topic by January 7, 2020. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these proposed regulations are Arslan Malik and Linda S.F. Marshall, of the Office of the Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in the development of the proposed regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX

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

Authority: 26 U.S.C. 7805 * * *

§ 1.401(a)(9)–5 [Amended]

■ **Par. 2.** Section 1.401(a)(9)–5 is amended by:

■ 1. Removing the language ''A–1 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(b)'' in its place.

■ 2. Removing the language ''A–2 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(c)'' in its place.

■ 3. Removing the language ''A–3 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(d)'' in its place.

§ 1.401(a)(9)–6 [Amended]

■ **Par. 3.** Section 1.401(a)(9)–6 is amended by:

■ 1. Removing the language ''A–1 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(b)'' in its place.

■ 2. Removing the language ''A–2 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(d)'' in its place.

■ 3. Removing the language ''A–3 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(e)'' in its place.

§ 1.401(a)(9)–8 [Amended]

■ **Par. 4.** Section 1.401(a)(9)–8 is amended by removing the language ''A–2 of § 1.401(a)(9)–9'' wherever it appears and adding ''§ 1.401(a)(9)–9(d)'' in its place.

■ **Par. 5.** Section 1.401(a)(9)–9 is amended to read as follows:

Section 1.401(a)(9)–9 Life Expectancy and Distribution Period Tables

(a) *In general.* This section specifies the life expectancy and applicable distribution period tables that apply for purposes of determining required minimum distributions under section 401(a)(9). Paragraphs (b), (c), and (d) of this section set forth these tables. Paragraph (e) of this section provides the mortality rates that are used to develop these tables. Paragraph (f) of this section provides applicability date rules.

(b) *Single Life Table.* Table 1 to paragraph (b), referred to as the Single Life Table, sets forth the life expectancy of an individual at each age.

TABLE 1 TO PARAGRAPH (b)—SINGLE LIFE TABLE

Age	Life expectancy
0	84.5
1	83.7
2	82.7
3	81.7
4	80.8
5	79.8
6	78.8
7	77.8
8	76.8
9	75.8
10	74.8
11	73.8
12	72.8
13	71.9
14	70.9
15	69.9
16	68.9
17	67.9
18	66.9
19	66.0
20	65.0
21	64.0
22	63.0
23	62.0
24	61.1
25	60.1
26	59.1
27	58.2
28	57.2
29	56.2
30	55.3
31	54.3
32	53.4
33	52.4
34	51.4
35	50.5
36	49.5
37	48.6
38	47.6
39	46.6
40	45.7
41	44.7
42	43.8
43	42.8
44	41.8
45	40.9
46	39.9
47	39.0
48	38.0
49	37.1
50	36.1
51	35.2
52	34.3
53	33.3
54	32.4
55	31.5

TABLE 1 TO PARAGRAPH (b)—SINGLE LIFE TABLE—Continued

Age	Life expectancy
56	30.6
57	29.7
58	28.8
59	27.9
60	27.1
61	26.2
62	25.3
63	24.5
64	23.6
65	22.8
66	22.0
67	21.2
68	20.4
69	19.5
70	18.7
71	17.9
72	17.1
73	16.3
74	15.6
75	14.8
76	14.0
77	13.3
78	12.6
79	11.9
80	11.2
81	10.5
82	9.9
83	9.2
84	8.6
85	8.1
86	7.5
87	7.0
88	6.6
89	6.1
90	5.7
91	5.3
92	4.9
93	4.6
94	4.2
95	3.9
96	3.7
97	3.4
98	3.2
99	3.0
100	2.8
101	2.6
102	2.5
103	2.3
104	2.2

TABLE 1 TO PARAGRAPH (b)—SINGLE LIFE TABLE—Continued

Age	Life expectancy
105	2.1
106	2.1
107	2.1
108	2.0
109	2.0
110	2.0
111	2.0
112	2.0
113	1.9
114	1.9
115	1.8
116	1.8
117	1.6
118	1.4
119	1.1
120 +	1.0

(c) *Uniform Lifetime Table.* Table 2 to paragraph (c), referred to as the Uniform Lifetime Table, sets forth the distribution period that applies for lifetime distributions to an employee in situations in which the employee's surviving spouse is not the sole designated beneficiary. This table is also used if the employee's surviving spouse is the sole designated beneficiary but is not more than 10 years younger than the employee.

TABLE 2 TO PARAGRAPH (c)—UNIFORM LIFETIME TABLE

Age of employee	Distribution period
70	29.1
71	28.2
72	27.3
73	26.4
74	25.5
75	24.6
76	23.7
77	22.8
78	21.9
79	21.0
80	20.2

TABLE 2 TO PARAGRAPH (c)—UNIFORM LIFETIME TABLE—Continued

Age of employee	Distribution period
81	19.3
82	18.4
83	17.6
84	16.8
85	16.0
86	15.2
87	14.4
88	13.6
89	12.9
90	12.1
91	11.4
92	10.8
93	10.1
94	9.5
95	8.9
96	8.3
97	7.8
98	7.3
99	6.8
100	6.4
101	5.9
102	5.6
103	5.2
104	4.9
105	4.6
106	4.3
107	4.1
108	3.9
109	3.7
110	3.5
111	3.4
112	3.2
113	3.1
114	3.0
115	2.9
116	2.8
117	2.7
118	2.5
119	2.3
120 +	2.0

(d) *Joint and Last Survivor Table.* Table 3 to paragraph (d), referred to as the Joint and Last Survivor Table, is used for determining the joint and last survivor life expectancy of two individuals.

TABLE 3 TO PARAGRAPH (d)—JOINT AND LAST SURVIVOR TABLE

Ages	0	1	2	3	4	5	6	7	8
0	91.8	91.4	90.9	90.5	90.1	89.7	89.3	89.0	88.7
1	91.4	90.9	90.4	89.9	89.5	89.1	88.7	88.3	88.0
2	90.9	90.4	89.9	89.4	88.9	88.5	88.1	87.7	87.3
3	90.5	89.9	89.4	88.9	88.4	87.9	87.5	87.1	86.7
4	90.1	89.5	88.9	88.4	87.9	87.4	86.9	86.5	86.1
5	89.7	89.1	88.5	87.9	87.4	86.9	86.4	85.9	85.5
6	89.3	88.7	88.1	87.5	86.9	86.4	85.9	85.4	84.9
7	89.0	88.3	87.7	87.1	86.5	85.9	85.4	84.9	84.4
8	88.7	88.0	87.3	86.7	86.1	85.5	84.9	84.4	83.9
9	88.4	87.7	87.0	86.3	85.7	85.1	84.5	83.9	83.4
10	88.1	87.4	86.7	86.0	85.3	84.7	84.1	83.5	82.9
11	87.9	87.1	86.4	85.7	85.0	84.4	83.7	83.1	82.5
12	87.6	86.9	86.1	85.4	84.7	84.0	83.4	82.7	82.1
13	87.4	86.7	85.9	85.1	84.4	83.7	83.0	82.4	81.7
14	87.2	86.4	85.7	84.9	84.2	83.4	82.7	82.0	81.4
15	87.0	86.2	85.5	84.7	83.9	83.2	82.4	81.7	81.0

TABLE 3 TO PARAGRAPH (d)—JOINT AND LAST SURVIVOR TABLE—Continued

Ages	0	1	2	3	4	5	6	7	8
16	86.9	86.1	85.3	84.5	83.7	82.9	82.2	81.4	80.7
17	86.7	85.9	85.1	84.3	83.5	82.7	81.9	81.2	80.4
18	86.6	85.7	84.9	84.1	83.3	82.5	81.7	80.9	80.2
19	86.4	85.6	84.7	83.9	83.1	82.3	81.5	80.7	79.9
20	86.3	85.5	84.6	83.8	82.9	82.1	81.3	80.5	79.7
21	86.2	85.3	84.5	83.6	82.8	81.9	81.1	80.3	79.5
22	86.1	85.2	84.3	83.5	82.6	81.8	80.9	80.1	79.3
23	86.0	85.1	84.2	83.4	82.5	81.6	80.8	79.9	79.1
24	85.9	85.0	84.1	83.2	82.4	81.5	80.6	79.8	78.9
25	85.8	84.9	84.0	83.1	82.2	81.4	80.5	79.6	78.8
26	85.7	84.8	83.9	83.0	82.1	81.2	80.4	79.5	78.6
27	85.6	84.8	83.9	82.9	82.0	81.1	80.3	79.4	78.5
28	85.6	84.7	83.8	82.9	82.0	81.0	80.1	79.3	78.4
29	85.5	84.6	83.7	82.8	81.9	81.0	80.1	79.2	78.3
30	85.4	84.6	83.6	82.7	81.8	80.9	80.0	79.1	78.2
31	85.4	84.5	83.6	82.6	81.7	80.8	79.9	79.0	78.1
32	85.3	84.4	83.5	82.6	81.6	80.7	79.8	78.9	78.0
33	85.3	84.4	83.5	82.5	81.6	80.7	79.7	78.8	77.9
34	85.2	84.3	83.4	82.5	81.5	80.6	79.7	78.7	77.8
35	85.2	84.3	83.4	82.4	81.5	80.5	79.6	78.7	77.7
36	85.2	84.3	83.3	82.4	81.4	80.5	79.5	78.6	77.7
37	85.1	84.2	83.3	82.3	81.4	80.4	79.5	78.5	77.6
38	85.1	84.2	83.2	82.3	81.3	80.4	79.4	78.5	77.6
39	85.1	84.2	83.2	82.3	81.3	80.3	79.4	78.4	77.5
40	85.0	84.1	83.2	82.2	81.3	80.3	79.3	78.4	77.4
41	85.0	84.1	83.1	82.2	81.2	80.3	79.3	78.4	77.4
42	85.0	84.1	83.1	82.2	81.2	80.2	79.3	78.3	77.4
43	84.9	84.0	83.1	82.1	81.2	80.2	79.2	78.3	77.3
44	84.9	84.0	83.1	82.1	81.1	80.2	79.2	78.2	77.3
45	84.9	84.0	83.0	82.1	81.1	80.1	79.2	78.2	77.3
46	84.9	84.0	83.0	82.1	81.1	80.1	79.2	78.2	77.2
47	84.9	84.0	83.0	82.0	81.1	80.1	79.1	78.2	77.2
48	84.8	83.9	83.0	82.0	81.0	80.1	79.1	78.1	77.2
49	84.8	83.9	83.0	82.0	81.0	80.1	79.1	78.1	77.1
50	84.8	83.9	82.9	82.0	81.0	80.0	79.1	78.1	77.1
51	84.8	83.9	82.9	82.0	81.0	80.0	79.0	78.1	77.1
52	84.8	83.9	82.9	81.9	81.0	80.0	79.0	78.0	77.1
53	84.8	83.9	82.9	81.9	81.0	80.0	79.0	78.0	77.1
54	84.7	83.9	82.9	81.9	80.9	80.0	79.0	78.0	77.0
55	84.7	83.8	82.9	81.9	80.9	79.9	79.0	78.0	77.0
56	84.7	83.8	82.9	81.9	80.9	79.9	79.0	78.0	77.0
57	84.7	83.8	82.9	81.9	80.9	79.9	78.9	78.0	77.0
58	84.7	83.8	82.8	81.9	80.9	79.9	78.9	78.0	77.0
59	84.7	83.8	82.8	81.9	80.9	79.9	78.9	77.9	77.0
60	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
61	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
62	84.7	83.8	82.8	81.8	80.9	79.9	78.9	77.9	76.9
63	84.6	83.8	82.8	81.8	80.8	79.9	78.9	77.9	76.9
64	84.6	83.8	82.8	81.8	80.8	79.9	78.9	77.9	76.9
65	84.6	83.8	82.8	81.8	80.8	79.8	78.9	77.9	76.9
66	84.6	83.7	82.8	81.8	80.8	79.8	78.9	77.9	76.9
67	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
68	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
69	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.9	76.9
70	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.8	76.9
71	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.8	76.9
72	84.6	83.7	82.8	81.8	80.8	79.8	78.8	77.8	76.9
73	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
74	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
75	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
76	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
77	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
78	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
79	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
80	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
81	84.6	83.7	82.7	81.8	80.8	79.8	78.8	77.8	76.8
82	84.6	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
83	84.6	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
84	84.6	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
85	84.6	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
86	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
87	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8

TABLE 3 TO PARAGRAPH (d)—JOINT AND LAST SURVIVOR TABLE—Continued

Ages	0	1	2	3	4	5	6	7	8
88	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
89	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
90	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
91	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
92	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
93	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
94	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
95	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
96	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
97	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
98	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
99	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
100	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
101	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
102	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
103	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
104	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
105	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
106	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
107	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
108	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
109	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
110	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
111	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
112	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
113	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
114	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
115	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
116	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
117	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
118	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
119	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8
120+	84.5	83.7	82.7	81.7	80.8	79.8	78.8	77.8	76.8

Ages	9	10	11	12	13	14	15	16	17
0	88.4	88.1	87.9	87.6	87.4	87.2	87.0	86.9	86.7
1	87.7	87.4	87.1	86.9	86.7	86.4	86.2	86.1	85.9
2	87.0	86.7	86.4	86.1	85.9	85.7	85.5	85.3	85.1
3	86.3	86.0	85.7	85.4	85.1	84.9	84.7	84.5	84.3
4	85.7	85.3	85.0	84.7	84.4	84.2	83.9	83.7	83.5
5	85.1	84.7	84.4	84.0	83.7	83.4	83.2	82.9	82.7
6	84.5	84.1	83.7	83.4	83.0	82.7	82.4	82.2	81.9
7	83.9	83.5	83.1	82.7	82.4	82.0	81.7	81.4	81.2
8	83.4	82.9	82.5	82.1	81.7	81.4	81.0	80.7	80.4
9	82.9	82.4	81.9	81.5	81.1	80.7	80.4	80.0	79.7
10	82.4	81.9	81.4	80.9	80.5	80.1	79.7	79.4	79.0
11	81.9	81.4	80.9	80.4	79.9	79.5	79.1	78.7	78.4
12	81.5	80.9	80.4	79.9	79.4	78.9	78.5	78.1	77.7
13	81.1	80.5	79.9	79.4	78.9	78.4	77.9	77.5	77.1
14	80.7	80.1	79.5	78.9	78.4	77.9	77.4	76.9	76.5
15	80.4	79.7	79.1	78.5	77.9	77.4	76.9	76.4	75.9
16	80.0	79.4	78.7	78.1	77.5	76.9	76.4	75.9	75.4
17	79.7	79.0	78.4	77.7	77.1	76.5	75.9	75.4	74.9
18	79.4	78.7	78.0	77.4	76.7	76.1	75.5	75.0	74.4
19	79.2	78.4	77.7	77.0	76.4	75.7	75.1	74.5	74.0
20	78.9	78.2	77.4	76.7	76.0	75.4	74.7	74.1	73.5
21	78.7	77.9	77.2	76.4	75.7	75.0	74.4	73.7	73.1
22	78.5	77.7	76.9	76.2	75.4	74.7	74.0	73.4	72.7
23	78.3	77.5	76.7	75.9	75.2	74.4	73.7	73.1	72.4
24	78.1	77.3	76.5	75.7	74.9	74.2	73.5	72.7	72.1
25	77.9	77.1	76.3	75.5	74.7	73.9	73.2	72.5	71.7
26	77.8	76.9	76.1	75.3	74.5	73.7	72.9	72.2	71.5
27	77.6	76.8	75.9	75.1	74.3	73.5	72.7	71.9	71.2
28	77.5	76.6	75.8	74.9	74.1	73.3	72.5	71.7	71.0
29	77.4	76.5	75.6	74.8	73.9	73.1	72.3	71.5	70.7
30	77.3	76.4	75.5	74.6	73.8	73.0	72.1	71.3	70.5
31	77.2	76.3	75.4	74.5	73.7	72.8	72.0	71.1	70.3
32	77.1	76.2	75.3	74.4	73.5	72.7	71.8	71.0	70.1
33	77.0	76.1	75.2	74.3	73.4	72.5	71.7	70.8	70.0
34	76.9	76.0	75.1	74.2	73.3	72.4	71.5	70.7	69.8

Ages	9	10	11	12	13	14	15	16	17
35	76.8	75.9	75.0	74.1	73.2	72.3	71.4	70.5	69.7
36	76.7	75.8	74.9	74.0	73.1	72.2	71.3	70.4	69.5
37	76.7	75.7	74.8	73.9	73.0	72.1	71.2	70.3	69.4
38	76.6	75.7	74.7	73.8	72.9	72.0	71.1	70.2	69.3
39	76.6	75.6	74.7	73.8	72.8	71.9	71.0	70.1	69.2
40	76.5	75.6	74.6	73.7	72.8	71.8	70.9	70.0	69.1
41	76.5	75.5	74.6	73.6	72.7	71.8	70.8	69.9	69.0
42	76.4	75.5	74.5	73.6	72.6	71.7	70.8	69.8	68.9
43	76.4	75.4	74.5	73.5	72.6	71.6	70.7	69.8	68.9
44	76.3	75.4	74.4	73.5	72.5	71.6	70.6	69.7	68.8
45	76.3	75.3	74.4	73.4	72.5	71.5	70.6	69.6	68.7
46	76.3	75.3	74.3	73.4	72.4	71.5	70.5	69.6	68.7
47	76.2	75.3	74.3	73.3	72.4	71.4	70.5	69.5	68.6
48	76.2	75.2	74.3	73.3	72.3	71.4	70.4	69.5	68.5
49	76.2	75.2	74.2	73.3	72.3	71.4	70.4	69.4	68.5
50	76.1	75.2	74.2	73.2	72.3	71.3	70.4	69.4	68.5
51	76.1	75.2	74.2	73.2	72.2	71.3	70.3	69.4	68.4
52	76.1	75.1	74.2	73.2	72.2	71.3	70.3	69.3	68.4
53	76.1	75.1	74.1	73.2	72.2	71.2	70.3	69.3	68.3
54	76.1	75.1	74.1	73.1	72.2	71.2	70.2	69.3	68.3
55	76.0	75.1	74.1	73.1	72.1	71.2	70.2	69.2	68.3
56	76.0	75.0	74.1	73.1	72.1	71.2	70.2	69.2	68.3
57	76.0	75.0	74.1	73.1	72.1	71.1	70.2	69.2	68.2
58	76.0	75.0	74.0	73.1	72.1	71.1	70.1	69.2	68.2
59	76.0	75.0	74.0	73.0	72.1	71.1	70.1	69.2	68.2
60	76.0	75.0	74.0	73.0	72.1	71.1	70.1	69.1	68.2
61	76.0	75.0	74.0	73.0	72.0	71.1	70.1	69.1	68.1
62	75.9	75.0	74.0	73.0	72.0	71.0	70.1	69.1	68.1
63	75.9	75.0	74.0	73.0	72.0	71.0	70.1	69.1	68.1
64	75.9	74.9	74.0	73.0	72.0	71.0	70.0	69.1	68.1
65	75.9	74.9	73.9	73.0	72.0	71.0	70.0	69.1	68.1
66	75.9	74.9	73.9	73.0	72.0	71.0	70.0	69.0	68.1
67	75.9	74.9	73.9	72.9	72.0	71.0	70.0	69.0	68.1
68	75.9	74.9	73.9	72.9	72.0	71.0	70.0	69.0	68.0
69	75.9	74.9	73.9	72.9	71.9	71.0	70.0	69.0	68.0
70	75.9	74.9	73.9	72.9	71.9	71.0	70.0	69.0	68.0
71	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
72	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
73	75.9	74.9	73.9	72.9	71.9	70.9	70.0	69.0	68.0
74	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
75	75.9	74.9	73.9	72.9	71.9	70.9	69.9	69.0	68.0
76	75.8	74.9	73.9	72.9	71.9	70.9	69.9	68.9	68.0
77	75.8	74.9	73.9	72.9	71.9	70.9	69.9	68.9	68.0
78	75.8	74.9	73.9	72.9	71.9	70.9	69.9	68.9	68.0
79	75.8	74.8	73.9	72.9	71.9	70.9	69.9	68.9	68.0
80	75.8	74.8	73.9	72.9	71.9	70.9	69.9	68.9	67.9
81	75.8	74.8	73.9	72.9	71.9	70.9	69.9	68.9	67.9
82	75.8	74.8	73.9	72.9	71.9	70.9	69.9	68.9	67.9
83	75.8	74.8	73.9	72.9	71.9	70.9	69.9	68.9	67.9
84	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
85	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
86	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
87	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
88	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
89	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
90	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
91	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
92	75.8	74.8	73.8	72.9	71.9	70.9	69.9	68.9	67.9
93	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
94	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
95	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
96	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
97	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
98	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
99	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
100	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
101	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
102	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
103	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
104	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
105	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
106	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
107	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
108	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9

Ages	9	10	11	12	13	14	15	16	17
109	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
110	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
111	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
112	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
113	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
114	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
115	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
116	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
117	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
118	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
119	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9
120+	75.8	74.8	73.8	72.8	71.9	70.9	69.9	68.9	67.9

Ages	18	19	20	21	22	23	24	25	26
0	86.6	86.4	86.3	86.2	86.1	86.0	85.9	85.8	85.7
1	85.7	85.6	85.5	85.3	85.2	85.1	85.0	84.9	84.8
2	84.9	84.7	84.6	84.5	84.3	84.2	84.1	84.0	83.9
3	84.1	83.9	83.8	83.6	83.5	83.4	83.2	83.1	83.0
4	83.3	83.1	82.9	82.8	82.6	82.5	82.4	82.2	82.1
5	82.5	82.3	82.1	81.9	81.8	81.6	81.5	81.4	81.2
6	81.7	81.5	81.3	81.1	80.9	80.8	80.6	80.5	80.4
7	80.9	80.7	80.5	80.3	80.1	79.9	79.8	79.6	79.5
8	80.2	79.9	79.7	79.5	79.3	79.1	78.9	78.8	78.6
9	79.4	79.2	78.9	78.7	78.5	78.3	78.1	77.9	77.8
10	78.7	78.4	78.2	77.9	77.7	77.5	77.3	77.1	76.9
11	78.0	77.7	77.4	77.2	76.9	76.7	76.5	76.3	76.1
12	77.4	77.0	76.7	76.4	76.2	75.9	75.7	75.5	75.3
13	76.7	76.4	76.0	75.7	75.4	75.2	74.9	74.7	74.5
14	76.1	75.7	75.4	75.0	74.7	74.4	74.2	73.9	73.7
15	75.5	75.1	74.7	74.4	74.0	73.7	73.5	73.2	72.9
16	75.0	74.5	74.1	73.7	73.4	73.1	72.7	72.5	72.2
17	74.4	74.0	73.5	73.1	72.7	72.4	72.1	71.7	71.5
18	73.9	73.4	73.0	72.5	72.1	71.7	71.4	71.1	70.8
19	73.4	72.9	72.4	72.0	71.5	71.1	70.8	70.4	70.1
20	73.0	72.4	71.9	71.4	71.0	70.5	70.1	69.8	69.4
21	72.5	72.0	71.4	70.9	70.4	70.0	69.5	69.1	68.8
22	72.1	71.5	71.0	70.4	69.9	69.4	69.0	68.5	68.1
23	71.7	71.1	70.5	70.0	69.4	68.9	68.4	68.0	67.6
24	71.4	70.8	70.1	69.5	69.0	68.4	67.9	67.4	67.0
25	71.1	70.4	69.8	69.1	68.5	68.0	67.4	66.9	66.5
26	70.8	70.1	69.4	68.8	68.1	67.6	67.0	66.5	65.9
27	70.5	69.8	69.1	68.4	67.8	67.2	66.6	66.0	65.5
28	70.2	69.5	68.8	68.1	67.4	66.8	66.2	65.6	65.0
29	70.0	69.2	68.5	67.8	67.1	66.4	65.8	65.2	64.6
30	69.7	69.0	68.2	67.5	66.8	66.1	65.4	64.8	64.2
31	69.5	68.7	68.0	67.2	66.5	65.8	65.1	64.4	63.8
32	69.3	68.5	67.7	67.0	66.2	65.5	64.8	64.1	63.4
33	69.1	68.3	67.5	66.7	66.0	65.2	64.5	63.8	63.1
34	69.0	68.1	67.3	66.5	65.8	65.0	64.2	63.5	62.8
35	68.8	68.0	67.2	66.3	65.5	64.8	64.0	63.3	62.5
36	68.7	67.8	67.0	66.2	65.4	64.6	63.8	63.0	62.3
37	68.5	67.7	66.8	66.0	65.2	64.4	63.6	62.8	62.0
38	68.4	67.6	66.7	65.8	65.0	64.2	63.4	62.6	61.8
39	68.3	67.4	66.6	65.7	64.9	64.0	63.2	62.4	61.6
40	68.2	67.3	66.4	65.6	64.7	63.9	63.0	62.2	61.4
41	68.1	67.2	66.3	65.4	64.6	63.7	62.9	62.0	61.2
42	68.0	67.1	66.2	65.3	64.5	63.6	62.7	61.9	61.0
43	67.9	67.0	66.1	65.2	64.3	63.5	62.6	61.7	60.9
44	67.9	66.9	66.0	65.1	64.2	63.4	62.5	61.6	60.7
45	67.8	66.9	66.0	65.0	64.1	63.3	62.4	61.5	60.6
46	67.7	66.8	65.9	65.0	64.1	63.2	62.3	61.4	60.5
47	67.7	66.7	65.8	64.9	64.0	63.1	62.2	61.3	60.4
48	67.6	66.7	65.7	64.8	63.9	63.0	62.1	61.2	60.3
49	67.6	66.6	65.7	64.8	63.8	62.9	62.0	61.1	60.2
50	67.5	66.6	65.6	64.7	63.8	62.8	61.9	61.0	60.1
51	67.5	66.5	65.6	64.6	63.7	62.8	61.9	60.9	60.0
52	67.4	66.5	65.5	64.6	63.7	62.7	61.8	60.9	60.0
53	67.4	66.4	65.5	64.5	63.6	62.7	61.7	60.8	59.9
54	67.4	66.4	65.4	64.5	63.6	62.6	61.7	60.7	59.8
55	67.3	66.4	65.4	64.5	63.5	62.6	61.6	60.7	59.8
56	67.3	66.3	65.4	64.4	63.5	62.5	61.6	60.6	59.7
57	67.3	66.3	65.3	64.4	63.4	62.5	61.5	60.6	59.7

Ages	18	19	20	21	22	23	24	25	26
58	67.2	66.3	65.3	64.4	63.4	62.5	61.5	60.6	59.6
59	67.2	66.3	65.3	64.3	63.4	62.4	61.5	60.5	59.6
60	67.2	66.2	65.3	64.3	63.3	62.4	61.4	60.5	59.5
61	67.2	66.2	65.2	64.3	63.3	62.4	61.4	60.5	59.5
62	67.2	66.2	65.2	64.3	63.3	62.3	61.4	60.4	59.5
63	67.1	66.2	65.2	64.2	63.3	62.3	61.4	60.4	59.4
64	67.1	66.2	65.2	64.2	63.3	62.3	61.3	60.4	59.4
65	67.1	66.1	65.2	64.2	63.2	62.3	61.3	60.3	59.4
66	67.1	66.1	65.2	64.2	63.2	62.2	61.3	60.3	59.4
67	67.1	66.1	65.1	64.2	63.2	62.2	61.3	60.3	59.3
68	67.1	66.1	65.1	64.2	63.2	62.2	61.3	60.3	59.3
69	67.1	66.1	65.1	64.1	63.2	62.2	61.2	60.3	59.3
70	67.0	66.1	65.1	64.1	63.2	62.2	61.2	60.3	59.3
71	67.0	66.1	65.1	64.1	63.1	62.2	61.2	60.2	59.3
72	67.0	66.1	65.1	64.1	63.1	62.2	61.2	60.2	59.3
73	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.3
74	67.0	66.0	65.1	64.1	63.1	62.1	61.2	60.2	59.2
75	67.0	66.0	65.0	64.1	63.1	62.1	61.2	60.2	59.2
76	67.0	66.0	65.0	64.1	63.1	62.1	61.2	60.2	59.2
77	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
78	67.0	66.0	65.0	64.1	63.1	62.1	61.1	60.2	59.2
79	67.0	66.0	65.0	64.0	63.1	62.1	61.1	60.2	59.2
80	67.0	66.0	65.0	64.0	63.1	62.1	61.1	60.2	59.2
81	67.0	66.0	65.0	64.0	63.1	62.1	61.1	60.1	59.2
82	67.0	66.0	65.0	64.0	63.1	62.1	61.1	60.1	59.2
83	67.0	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.2
84	67.0	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.2
85	67.0	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.2
86	67.0	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.2
87	66.9	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.1
88	66.9	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.1
89	66.9	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.1
90	66.9	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.1
91	66.9	66.0	65.0	64.0	63.0	62.1	61.1	60.1	59.1
92	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
93	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
94	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
95	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
96	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
97	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
98	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
99	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
100	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
101	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
102	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
103	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
104	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
105	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
106	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
107	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
108	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
109	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
110	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
111	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
112	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
113	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
114	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
115	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
116	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
117	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
118	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
119	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1
120+	66.9	66.0	65.0	64.0	63.0	62.0	61.1	60.1	59.1

Ages	27	28	29	30	31	32	33	34	35
0	85.6	85.6	85.5	85.4	85.4	85.3	85.3	85.2	85.2
1	84.8	84.7	84.6	84.6	84.5	84.4	84.4	84.3	84.3
2	83.9	83.8	83.7	83.6	83.6	83.5	83.5	83.4	83.4
3	82.9	82.9	82.8	82.7	82.6	82.6	82.5	82.5	82.4
4	82.0	82.0	81.9	81.8	81.7	81.6	81.6	81.5	81.5
5	81.1	81.0	81.0	80.9	80.8	80.7	80.7	80.6	80.5
6	80.3	80.1	80.1	80.0	79.9	79.8	79.7	79.7	79.6

Ages	27	28	29	30	31	32	33	34	35
7	79.4	79.3	79.2	79.1	79.0	78.9	78.8	78.7	78.7
8	78.5	78.4	78.3	78.2	78.1	78.0	77.9	77.8	77.7
9	77.6	77.5	77.4	77.3	77.2	77.1	77.0	76.9	76.8
10	76.8	76.6	76.5	76.4	76.3	76.2	76.1	76.0	75.9
11	75.9	75.8	75.6	75.5	75.4	75.3	75.2	75.1	75.0
12	75.1	74.9	74.8	74.6	74.5	74.4	74.3	74.2	74.1
13	74.3	74.1	73.9	73.8	73.7	73.5	73.4	73.3	73.2
14	73.5	73.3	73.1	73.0	72.8	72.7	72.5	72.4	72.3
15	72.7	72.5	72.3	72.1	72.0	71.8	71.7	71.5	71.4
16	71.9	71.7	71.5	71.3	71.1	71.0	70.8	70.7	70.5
17	71.2	71.0	70.7	70.5	70.3	70.1	70.0	69.8	69.7
18	70.5	70.2	70.0	69.7	69.5	69.3	69.1	69.0	68.8
19	69.8	69.5	69.2	69.0	68.7	68.5	68.3	68.1	68.0
20	69.1	68.8	68.5	68.2	68.0	67.7	67.5	67.3	67.2
21	68.4	68.1	67.8	67.5	67.2	67.0	66.7	66.5	66.3
22	67.8	67.4	67.1	66.8	66.5	66.2	66.0	65.8	65.5
23	67.2	66.8	66.4	66.1	65.8	65.5	65.2	65.0	64.8
24	66.6	66.2	65.8	65.4	65.1	64.8	64.5	64.2	64.0
25	66.0	65.6	65.2	64.8	64.4	64.1	63.8	63.5	63.3
26	65.5	65.0	64.6	64.2	63.8	63.4	63.1	62.8	62.5
27	65.0	64.5	64.0	63.6	63.2	62.8	62.5	62.1	61.8
28	64.5	64.0	63.5	63.0	62.6	62.2	61.8	61.5	61.1
29	64.0	63.5	63.0	62.5	62.0	61.6	61.2	60.8	60.5
30	63.6	63.0	62.5	62.0	61.5	61.0	60.6	60.2	59.8
31	63.2	62.6	62.0	61.5	61.0	60.5	60.1	59.6	59.2
32	62.8	62.2	61.6	61.0	60.5	60.0	59.5	59.1	58.6
33	62.5	61.8	61.2	60.6	60.1	59.5	59.0	58.5	58.1
34	62.1	61.5	60.8	60.2	59.6	59.1	58.5	58.0	57.5
35	61.8	61.1	60.5	59.8	59.2	58.6	58.1	57.5	57.0
36	61.5	60.8	60.1	59.5	58.8	58.2	57.6	57.1	56.6
37	61.3	60.5	59.8	59.2	58.5	57.9	57.2	56.7	56.1
38	61.0	60.3	59.6	58.9	58.2	57.5	56.9	56.3	55.7
39	60.8	60.0	59.3	58.6	57.9	57.2	56.5	55.9	55.3
40	60.6	59.8	59.0	58.3	57.6	56.9	56.2	55.5	54.9
41	60.4	59.6	58.8	58.1	57.3	56.6	55.9	55.2	54.5
42	60.2	59.4	58.6	57.8	57.1	56.3	55.6	54.9	54.2
43	60.1	59.2	58.4	57.6	56.8	56.1	55.3	54.6	53.9
44	59.9	59.1	58.2	57.4	56.6	55.9	55.1	54.4	53.6
45	59.8	58.9	58.1	57.3	56.4	55.7	54.9	54.1	53.4
46	59.6	58.8	57.9	57.1	56.3	55.5	54.7	53.9	53.1
47	59.5	58.6	57.8	56.9	56.1	55.3	54.5	53.7	52.9
48	59.4	58.5	57.7	56.8	56.0	55.1	54.3	53.5	52.7
49	59.3	58.4	57.5	56.7	55.8	55.0	54.1	53.3	52.5
50	59.2	58.3	57.4	56.6	55.7	54.8	54.0	53.2	52.3
51	59.1	58.2	57.3	56.5	55.6	54.7	53.9	53.0	52.2
52	59.0	58.1	57.2	56.4	55.5	54.6	53.7	52.9	52.0
53	59.0	58.1	57.2	56.3	55.4	54.5	53.6	52.7	51.9
54	58.9	58.0	57.1	56.2	55.3	54.4	53.5	52.6	51.8
55	58.8	57.9	57.0	56.1	55.2	54.3	53.4	52.5	51.7
56	58.8	57.9	56.9	56.0	55.1	54.2	53.3	52.4	51.6
57	58.7	57.8	56.9	56.0	55.0	54.1	53.2	52.3	51.5
58	58.7	57.7	56.8	55.9	55.0	54.1	53.2	52.3	51.4
59	58.6	57.7	56.8	55.8	54.9	54.0	53.1	52.2	51.3
60	58.6	57.7	56.7	55.8	54.9	53.9	53.0	52.1	51.2
61	58.6	57.6	56.7	55.7	54.8	53.9	53.0	52.1	51.1
62	58.5	57.6	56.6	55.7	54.8	53.8	52.9	52.0	51.1
63	58.5	57.5	56.6	55.7	54.7	53.8	52.9	51.9	51.0
64	58.5	57.5	56.6	55.6	54.7	53.8	52.8	51.9	51.0
65	58.4	57.5	56.5	55.6	54.7	53.7	52.8	51.9	50.9
66	58.4	57.5	56.5	55.6	54.6	53.7	52.7	51.8	50.9
67	58.4	57.4	56.5	55.5	54.6	53.7	52.7	51.8	50.8
68	58.4	57.4	56.5	55.5	54.6	53.6	52.7	51.7	50.8
69	58.4	57.4	56.4	55.5	54.5	53.6	52.7	51.7	50.8
70	58.3	57.4	56.4	55.5	54.5	53.6	52.6	51.7	50.7
71	58.3	57.4	56.4	55.5	54.5	53.6	52.6	51.7	50.7
72	58.3	57.3	56.4	55.4	54.5	53.5	52.6	51.6	50.7
73	58.3	57.3	56.4	55.4	54.5	53.5	52.6	51.6	50.7
74	58.3	57.3	56.4	55.4	54.5	53.5	52.5	51.6	50.6
75	58.3	57.3	56.3	55.4	54.4	53.5	52.5	51.6	50.6
76	58.3	57.3	56.3	55.4	54.4	53.5	52.5	51.6	50.6
77	58.2	57.3	56.3	55.4	54.4	53.5	52.5	51.6	50.6
78	58.2	57.3	56.3	55.4	54.4	53.4	52.5	51.5	50.6
79	58.2	57.3	56.3	55.4	54.4	53.4	52.5	51.5	50.6
80	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6

Ages	27	28	29	30	31	32	33	34	35
81	58.2	57.3	56.3	55.3	54.4	53.4	52.5	51.5	50.6
82	58.2	57.2	56.3	55.3	54.4	53.4	52.5	51.5	50.5
83	58.2	57.2	56.3	55.3	54.4	53.4	52.5	51.5	50.5
84	58.2	57.2	56.3	55.3	54.4	53.4	52.4	51.5	50.5
85	58.2	57.2	56.3	55.3	54.4	53.4	52.4	51.5	50.5
86	58.2	57.2	56.3	55.3	54.3	53.4	52.4	51.5	50.5
87	58.2	57.2	56.3	55.3	54.3	53.4	52.4	51.5	50.5
88	58.2	57.2	56.3	55.3	54.3	53.4	52.4	51.5	50.5
89	58.2	57.2	56.3	55.3	54.3	53.4	52.4	51.5	50.5
90	58.2	57.2	56.3	55.3	54.3	53.4	52.4	51.5	50.5
91	58.2	57.2	56.3	55.3	54.3	53.4	52.4	51.5	50.5
92	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
93	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
94	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
95	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
96	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
97	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
98	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
99	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
100	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.5	50.5
101	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
102	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
103	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
104	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
105	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
106	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
107	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
108	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
109	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
110	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
111	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
112	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
113	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
114	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
115	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
116	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
117	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
118	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
119	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5
120+	58.2	57.2	56.2	55.3	54.3	53.4	52.4	51.4	50.5

Ages	36	37	38	39	40	41	42	43	44
0	85.2	85.1	85.1	85.1	85.0	85.0	85.0	84.9	84.9
1	84.3	84.2	84.2	84.2	84.1	84.1	84.1	84.0	84.0
2	83.3	83.3	83.2	83.2	83.2	83.1	83.1	83.1	83.1
3	82.4	82.3	82.3	82.3	82.2	82.2	82.2	82.1	82.1
4	81.4	81.4	81.3	81.3	81.3	81.2	81.2	81.2	81.1
5	80.5	80.4	80.4	80.3	80.3	80.3	80.2	80.2	80.2
6	79.5	79.5	79.4	79.4	79.3	79.3	79.3	79.2	79.2
7	78.6	78.5	78.5	78.4	78.4	78.4	78.3	78.3	78.2
8	77.7	77.6	77.6	77.5	77.4	77.4	77.4	77.3	77.3
9	76.7	76.7	76.6	76.6	76.5	76.5	76.4	76.4	76.3
10	75.8	75.7	75.7	75.6	75.6	75.5	75.5	75.4	75.4
11	74.9	74.8	74.7	74.7	74.6	74.6	74.5	74.5	74.4
12	74.0	73.9	73.8	73.8	73.7	73.6	73.6	73.5	73.5
13	73.1	73.0	72.9	72.8	72.8	72.7	72.6	72.6	72.5
14	72.2	72.1	72.0	71.9	71.8	71.8	71.7	71.6	71.6
15	71.3	71.2	71.1	71.0	70.9	70.8	70.8	70.7	70.6
16	70.4	70.3	70.2	70.1	70.0	69.9	69.8	69.8	69.7
17	69.5	69.4	69.3	69.2	69.1	69.0	68.9	68.9	68.8
18	68.7	68.5	68.4	68.3	68.2	68.1	68.0	67.9	67.9
19	67.8	67.7	67.6	67.4	67.3	67.2	67.1	67.0	66.9
20	67.0	66.8	66.7	66.6	66.4	66.3	66.2	66.1	66.0
21	66.2	66.0	65.8	65.7	65.6	65.4	65.3	65.2	65.1
22	65.4	65.2	65.0	64.9	64.7	64.6	64.5	64.3	64.2
23	64.6	64.4	64.2	64.0	63.9	63.7	63.6	63.5	63.4
24	63.8	63.6	63.4	63.2	63.0	62.9	62.7	62.6	62.5
25	63.0	62.8	62.6	62.4	62.2	62.0	61.9	61.7	61.6
26	62.3	62.0	61.8	61.6	61.4	61.2	61.0	60.9	60.7
27	61.5	61.3	61.0	60.8	60.6	60.4	60.2	60.1	59.9
28	60.8	60.5	60.3	60.0	59.8	59.6	59.4	59.2	59.1
29	60.1	59.8	59.6	59.3	59.0	58.8	58.6	58.4	58.2

Ages	36	37	38	39	40	41	42	43	44
30	59.5	59.2	58.9	58.6	58.3	58.1	57.8	57.6	57.4
31	58.8	58.5	58.2	57.9	57.6	57.3	57.1	56.8	56.6
32	58.2	57.9	57.5	57.2	56.9	56.6	56.3	56.1	55.9
33	57.6	57.2	56.9	56.5	56.2	55.9	55.6	55.3	55.1
34	57.1	56.7	56.3	55.9	55.5	55.2	54.9	54.6	54.4
35	56.6	56.1	55.7	55.3	54.9	54.5	54.2	53.9	53.6
36	56.0	55.6	55.1	54.7	54.3	53.9	53.6	53.2	52.9
37	55.6	55.1	54.6	54.1	53.7	53.3	52.9	52.6	52.2
38	55.1	54.6	54.1	53.6	53.1	52.7	52.3	51.9	51.6
39	54.7	54.1	53.6	53.1	52.6	52.1	51.7	51.3	50.9
40	54.3	53.7	53.1	52.6	52.1	51.6	51.2	50.7	50.3
41	53.9	53.3	52.7	52.1	51.6	51.1	50.6	50.2	49.7
42	53.6	52.9	52.3	51.7	51.2	50.6	50.1	49.6	49.2
43	53.2	52.6	51.9	51.3	50.7	50.2	49.6	49.1	48.6
44	52.9	52.2	51.6	50.9	50.3	49.7	49.2	48.6	48.1
45	52.6	51.9	51.3	50.6	50.0	49.3	48.7	48.2	47.7
46	52.4	51.7	50.9	50.3	49.6	49.0	48.3	47.8	47.2
47	52.1	51.4	50.7	50.0	49.3	48.6	48.0	47.4	46.8
48	51.9	51.2	50.4	49.7	49.0	48.3	47.6	47.0	46.4
49	51.7	50.9	50.2	49.4	48.7	48.0	47.3	46.6	46.0
50	51.5	50.7	49.9	49.2	48.4	47.7	47.0	46.3	45.7
51	51.4	50.5	49.7	49.0	48.2	47.5	46.7	46.0	45.3
52	51.2	50.4	49.6	48.8	48.0	47.2	46.5	45.7	45.0
53	51.0	50.2	49.4	48.6	47.8	47.0	46.2	45.5	44.8
54	50.9	50.1	49.2	48.4	47.6	46.8	46.0	45.3	44.5
55	50.8	49.9	49.1	48.2	47.4	46.6	45.8	45.0	44.3
56	50.7	49.8	48.9	48.1	47.3	46.4	45.6	44.8	44.1
57	50.6	49.7	48.8	48.0	47.1	46.3	45.5	44.7	43.9
58	50.5	49.6	48.7	47.8	47.0	46.1	45.3	44.5	43.7
59	50.4	49.5	48.6	47.7	46.9	46.0	45.2	44.3	43.5
60	50.3	49.4	48.5	47.6	46.8	45.9	45.0	44.2	43.4
61	50.2	49.3	48.4	47.5	46.7	45.8	44.9	44.1	43.2
62	50.2	49.3	48.4	47.5	46.6	45.7	44.8	43.9	43.1
63	50.1	49.2	48.3	47.4	46.5	45.6	44.7	43.8	43.0
64	50.0	49.1	48.2	47.3	46.4	45.5	44.6	43.7	42.9
65	50.0	49.1	48.2	47.2	46.3	45.4	44.5	43.6	42.8
66	50.0	49.0	48.1	47.2	46.3	45.4	44.5	43.6	42.7
67	49.9	49.0	48.0	47.1	46.2	45.3	44.4	43.5	42.6
68	49.9	48.9	48.0	47.1	46.2	45.2	44.3	43.4	42.5
69	49.8	48.9	48.0	47.0	46.1	45.2	44.3	43.3	42.4
70	49.8	48.9	47.9	47.0	46.1	45.1	44.2	43.3	42.4
71	49.8	48.8	47.9	47.0	46.0	45.1	44.2	43.2	42.3
72	49.7	48.8	47.9	46.9	46.0	45.0	44.1	43.2	42.3
73	49.7	48.8	47.8	46.9	45.9	45.0	44.1	43.1	42.2
74	49.7	48.8	47.8	46.9	45.9	45.0	44.0	43.1	42.2
75	49.7	48.7	47.8	46.8	45.9	44.9	44.0	43.1	42.1
76	49.7	48.7	47.8	46.8	45.9	44.9	44.0	43.0	42.1
77	49.6	48.7	47.7	46.8	45.8	44.9	43.9	43.0	42.1
78	49.6	48.7	47.7	46.8	45.8	44.9	43.9	43.0	42.0
79	49.6	48.7	47.7	46.8	45.8	44.9	43.9	43.0	42.0
80	49.6	48.7	47.7	46.7	45.8	44.8	43.9	42.9	42.0
81	49.6	48.6	47.7	46.7	45.8	44.8	43.9	42.9	42.0
82	49.6	48.6	47.7	46.7	45.8	44.8	43.9	42.9	42.0
83	49.6	48.6	47.7	46.7	45.8	44.8	43.8	42.9	41.9
84	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
85	49.6	48.6	47.7	46.7	45.7	44.8	43.8	42.9	41.9
86	49.6	48.6	47.6	46.7	45.7	44.8	43.8	42.9	41.9
87	49.6	48.6	47.6	46.7	45.7	44.8	43.8	42.9	41.9
88	49.6	48.6	47.6	46.7	45.7	44.8	43.8	42.8	41.9
89	49.6	48.6	47.6	46.7	45.7	44.8	43.8	42.8	41.9
90	49.5	48.6	47.6	46.7	45.7	44.8	43.8	42.8	41.9
91	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
92	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
93	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
94	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
95	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
96	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
97	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
98	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
99	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
100	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
101	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
102	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
103	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9

Ages	36	37	38	39	40	41	42	43	44
104	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
105	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
106	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
107	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
108	49.5	48.6	47.6	46.7	45.7	44.7	43.8	42.8	41.9
109	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
110	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
111	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
112	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
113	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
114	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
115	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.9
116	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.8
117	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.8
118	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.8
119	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.8
120+	49.5	48.6	47.6	46.6	45.7	44.7	43.8	42.8	41.8

Ages	45	46	47	48	49	50	51	52	53
0	84.9	84.9	84.9	84.8	84.8	84.8	84.8	84.8	84.8
1	84.0	84.0	84.0	83.9	83.9	83.9	83.9	83.9	83.9
2	83.0	83.0	83.0	83.0	83.0	82.9	82.9	82.9	82.9
3	82.1	82.1	82.0	82.0	82.0	82.0	82.0	81.9	81.9
4	81.1	81.1	81.1	81.0	81.0	81.0	81.0	81.0	81.0
5	80.1	80.1	80.1	80.1	80.1	80.0	80.0	80.0	80.0
6	79.2	79.2	79.1	79.1	79.1	79.1	79.0	79.0	79.0
7	78.2	78.2	78.2	78.1	78.1	78.1	78.1	78.0	78.0
8	77.3	77.2	77.2	77.2	77.1	77.1	77.1	77.1	77.1
9	76.3	76.3	76.2	76.2	76.2	76.1	76.1	76.1	76.1
10	75.3	75.3	75.3	75.2	75.2	75.2	75.2	75.1	75.1
11	74.4	74.3	74.3	74.3	74.2	74.2	74.2	74.2	74.1
12	73.4	73.4	73.3	73.3	73.3	73.2	73.2	73.2	73.2
13	72.5	72.4	72.4	72.3	72.3	72.3	72.2	72.2	72.2
14	71.5	71.5	71.4	71.4	71.4	71.3	71.3	71.3	71.2
15	70.6	70.5	70.5	70.4	70.4	70.4	70.3	70.3	70.3
16	69.6	69.6	69.5	69.5	69.4	69.4	69.4	69.3	69.3
17	68.7	68.7	68.6	68.5	68.5	68.5	68.4	68.4	68.3
18	67.8	67.7	67.7	67.6	67.6	67.5	67.5	67.4	67.4
19	66.9	66.8	66.7	66.7	66.6	66.6	66.5	66.5	66.4
20	66.0	65.9	65.8	65.7	65.7	65.6	65.6	65.5	65.5
21	65.0	65.0	64.9	64.8	64.8	64.7	64.6	64.6	64.5
22	64.1	64.1	64.0	63.9	63.8	63.8	63.7	63.7	63.6
23	63.3	63.2	63.1	63.0	62.9	62.8	62.8	62.7	62.7
24	62.4	62.3	62.2	62.1	62.0	61.9	61.9	61.8	61.7
25	61.5	61.4	61.3	61.2	61.1	61.0	60.9	60.9	60.8
26	60.6	60.5	60.4	60.3	60.2	60.1	60.0	60.0	59.9
27	59.8	59.6	59.5	59.4	59.3	59.2	59.1	59.0	59.0
28	58.9	58.8	58.6	58.5	58.4	58.3	58.2	58.1	58.1
29	58.1	57.9	57.8	57.7	57.5	57.4	57.3	57.2	57.2
30	57.3	57.1	56.9	56.8	56.7	56.6	56.5	56.4	56.3
31	56.4	56.3	56.1	56.0	55.8	55.7	55.6	55.5	55.4
32	55.7	55.5	55.3	55.1	55.0	54.8	54.7	54.6	54.5
33	54.9	54.7	54.5	54.3	54.1	54.0	53.9	53.7	53.6
34	54.1	53.9	53.7	53.5	53.3	53.2	53.0	52.9	52.7
35	53.4	53.1	52.9	52.7	52.5	52.3	52.2	52.0	51.9
36	52.6	52.4	52.1	51.9	51.7	51.5	51.4	51.2	51.0
37	51.9	51.7	51.4	51.2	50.9	50.7	50.5	50.4	50.2
38	51.3	50.9	50.7	50.4	50.2	49.9	49.7	49.6	49.4
39	50.6	50.3	50.0	49.7	49.4	49.2	49.0	48.8	48.6
40	50.0	49.6	49.3	49.0	48.7	48.4	48.2	48.0	47.8
41	49.3	49.0	48.6	48.3	48.0	47.7	47.5	47.2	47.0
42	48.7	48.3	48.0	47.6	47.3	47.0	46.7	46.5	46.2
43	48.2	47.8	47.4	47.0	46.6	46.3	46.0	45.7	45.5
44	47.7	47.2	46.8	46.4	46.0	45.7	45.3	45.0	44.8
45	47.1	46.7	46.2	45.8	45.4	45.0	44.7	44.4	44.1
46	46.7	46.2	45.7	45.2	44.8	44.4	44.0	43.7	43.4
47	46.2	45.7	45.2	44.7	44.2	43.8	43.4	43.1	42.7
48	45.8	45.2	44.7	44.2	43.7	43.3	42.8	42.4	42.1
49	45.4	44.8	44.2	43.7	43.2	42.7	42.3	41.9	41.5
50	45.0	44.4	43.8	43.3	42.7	42.2	41.7	41.3	40.9
51	44.7	44.0	43.4	42.8	42.3	41.7	41.2	40.8	40.3
52	44.4	43.7	43.1	42.4	41.9	41.3	40.8	40.3	39.8

Ages	45	46	47	48	49	50	51	52	53
53	44.1	43.4	42.7	42.1	41.5	40.9	40.3	39.8	39.3
54	43.8	43.1	42.4	41.7	41.1	40.5	39.9	39.3	38.8
55	43.5	42.8	42.1	41.4	40.8	40.1	39.5	38.9	38.4
56	43.3	42.5	41.8	41.1	40.4	39.8	39.1	38.5	38.0
57	43.1	42.3	41.6	40.8	40.1	39.5	38.8	38.2	37.6
58	42.9	42.1	41.3	40.6	39.9	39.2	38.5	37.8	37.2
59	42.7	41.9	41.1	40.4	39.6	38.9	38.2	37.5	36.9
60	42.5	41.7	40.9	40.1	39.4	38.6	37.9	37.2	36.6
61	42.4	41.6	40.7	40.0	39.2	38.4	37.7	37.0	36.3
62	42.2	41.4	40.6	39.8	39.0	38.2	37.5	36.7	36.0
63	42.1	41.3	40.4	39.6	38.8	38.0	37.2	36.5	35.8
64	42.0	41.1	40.3	39.5	38.6	37.8	37.0	36.3	35.5
65	41.9	41.0	40.2	39.3	38.5	37.7	36.9	36.1	35.3
66	41.8	40.9	40.0	39.2	38.4	37.5	36.7	35.9	35.1
67	41.7	40.8	39.9	39.1	38.2	37.4	36.6	35.7	35.0
68	41.6	40.7	39.8	39.0	38.1	37.3	36.4	35.6	34.8
69	41.5	40.6	39.8	38.9	38.0	37.1	36.3	35.5	34.6
70	41.5	40.6	39.7	38.8	37.9	37.0	36.2	35.3	34.5
71	41.4	40.5	39.6	38.7	37.8	36.9	36.1	35.2	34.4
72	41.3	40.4	39.5	38.6	37.7	36.9	36.0	35.1	34.3
73	41.3	40.4	39.5	38.6	37.7	36.8	35.9	35.0	34.2
74	41.2	40.3	39.4	38.5	37.6	36.7	35.8	34.9	34.1
75	41.2	40.3	39.4	38.4	37.5	36.6	35.7	34.9	34.0
76	41.2	40.2	39.3	38.4	37.5	36.6	35.7	34.8	33.9
77	41.1	40.2	39.3	38.4	37.4	36.5	35.6	34.7	33.9
78	41.1	40.2	39.2	38.3	37.4	36.5	35.6	34.7	33.8
79	41.1	40.1	39.2	38.3	37.4	36.4	35.5	34.6	33.7
80	41.1	40.1	39.2	38.2	37.3	36.4	35.5	34.6	33.7
81	41.0	40.1	39.1	38.2	37.3	36.4	35.4	34.5	33.6
82	41.0	40.1	39.1	38.2	37.3	36.3	35.4	34.5	33.6
83	41.0	40.0	39.1	38.2	37.2	36.3	35.4	34.5	33.6
84	41.0	40.0	39.1	38.1	37.2	36.3	35.4	34.4	33.5
85	41.0	40.0	39.1	38.1	37.2	36.3	35.3	34.4	33.5
86	41.0	40.0	39.1	38.1	37.2	36.2	35.3	34.4	33.5
87	40.9	40.0	39.0	38.1	37.2	36.2	35.3	34.4	33.5
88	40.9	40.0	39.0	38.1	37.1	36.2	35.3	34.4	33.4
89	40.9	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
90	40.9	40.0	39.0	38.1	37.1	36.2	35.3	34.3	33.4
91	40.9	40.0	39.0	38.1	37.1	36.2	35.2	34.3	33.4
92	40.9	40.0	39.0	38.1	37.1	36.2	35.2	34.3	33.4
93	40.9	40.0	39.0	38.1	37.1	36.2	35.2	34.3	33.4
94	40.9	40.0	39.0	38.1	37.1	36.2	35.2	34.3	33.4
95	40.9	40.0	39.0	38.0	37.1	36.2	35.2	34.3	33.4
96	40.9	39.9	39.0	38.0	37.1	36.2	35.2	34.3	33.4
97	40.9	39.9	39.0	38.0	37.1	36.2	35.2	34.3	33.4
98	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.4
99	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
100	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
101	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
102	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
103	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
104	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
105	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
106	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
107	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
108	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
109	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
110	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
111	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
112	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
113	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
114	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
115	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
116	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
117	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
118	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
119	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3
120+	40.9	39.9	39.0	38.0	37.1	36.1	35.2	34.3	33.3

Ages	54	55	56	57	58	59	60	61	62
0	84.7	84.7	84.7	84.7	84.7	84.7	84.7	84.7	84.7
1	83.9x	83.8	83.8	83.8	83.8	83.8	83.8	83.8	83.8

Ages	54	55	56	57	58	59	60	61	62
2	82.9	82.9	82.9	82.9	82.8	82.8	82.8	82.8	82.8
3	81.9	81.9	81.9	81.9	81.9	81.9	81.8	81.8	81.8
4	80.9	80.9	80.9	80.9	80.9	80.9	80.9	80.9	80.9
5	80.0	79.9	79.9	79.9	79.9	79.9	79.9	79.9	79.9
6	79.0	79.0	79.0	78.9	78.9	78.9	78.9	78.9	78.9
7	78.0	78.0	78.0	78.0	78.0	77.9	77.9	77.9	77.9
8	77.0	77.0	77.0	77.0	77.0	77.0	76.9	76.9	76.9
9	76.1	76.0	76.0	76.0	76.0	76.0	76.0	76.0	75.9
10	75.1	75.1	75.0	75.0	75.0	75.0	75.0	75.0	75.0
11	74.1	74.1	74.1	74.1	74.0	74.0	74.0	74.0	74.0
12	73.1	73.1	73.1	73.1	73.1	73.0	73.0	73.0	73.0
13	72.2	72.1	72.1	72.1	72.1	72.1	72.1	72.0	72.0
14	71.2	71.2	71.2	71.1	71.1	71.1	71.1	71.1	71.0
15	70.2	70.2	70.2	70.2	70.1	70.1	70.1	70.1	70.1
16	69.3	69.2	69.2	69.2	69.2	69.2	69.1	69.1	69.1
17	68.3	68.3	68.3	68.2	68.2	68.2	68.2	68.1	68.1
18	67.4	67.3	67.3	67.3	67.2	67.2	67.2	67.2	67.2
19	66.4	66.4	66.3	66.3	66.3	66.3	66.2	66.2	66.2
20	65.4	65.4	65.4	65.3	65.3	65.3	65.3	65.2	65.2
21	64.5	64.5	64.4	64.4	64.4	64.3	64.3	64.3	64.3
22	63.6	63.5	63.5	63.4	63.4	63.4	63.3	63.3	63.3
23	62.6	62.6	62.5	62.5	62.5	62.4	62.4	62.4	62.3
24	61.7	61.6	61.6	61.5	61.5	61.5	61.4	61.4	61.4
25	60.7	60.7	60.6	60.6	60.6	60.5	60.5	60.5	60.4
26	59.8	59.8	59.7	59.7	59.6	59.6	59.5	59.5	59.5
27	58.9	58.8	58.8	58.7	58.7	58.6	58.6	58.6	58.5
28	58.0	57.9	57.9	57.8	57.7	57.7	57.7	57.6	57.6
29	57.1	57.0	56.9	56.9	56.8	56.8	56.7	56.7	56.6
30	56.2	56.1	56.0	56.0	55.9	55.8	55.8	55.7	55.7
31	55.3	55.2	55.1	55.0	55.0	54.9	54.9	54.8	54.8
32	54.4	54.3	54.2	54.1	54.1	54.0	53.9	53.9	53.8
33	53.5	53.4	53.3	53.2	53.2	53.1	53.0	53.0	52.9
34	52.6	52.5	52.4	52.3	52.3	52.2	52.1	52.1	52.0
35	51.8	51.7	51.6	51.5	51.4	51.3	51.2	51.1	51.1
36	50.9	50.8	50.7	50.6	50.5	50.4	50.3	50.2	50.2
37	50.1	49.9	49.8	49.7	49.6	49.5	49.4	49.3	49.3
38	49.2	49.1	48.9	48.8	48.7	48.6	48.5	48.4	48.4
39	48.4	48.2	48.1	48.0	47.8	47.7	47.6	47.5	47.5
40	47.6	47.4	47.3	47.1	47.0	46.9	46.8	46.7	46.6
41	46.8	46.6	46.4	46.3	46.1	46.0	45.9	45.8	45.7
42	46.0	45.8	45.6	45.5	45.3	45.2	45.0	44.9	44.8
43	45.3	45.0	44.8	44.7	44.5	44.3	44.2	44.1	43.9
44	44.5	44.3	44.1	43.9	43.7	43.5	43.4	43.2	43.1
45	43.8	43.5	43.3	43.1	42.9	42.7	42.5	42.4	42.2
46	43.1	42.8	42.5	42.3	42.1	41.9	41.7	41.6	41.4
47	42.4	42.1	41.8	41.6	41.3	41.1	40.9	40.7	40.6
48	41.7	41.4	41.1	40.8	40.6	40.4	40.1	40.0	39.8
49	41.1	40.8	40.4	40.1	39.9	39.6	39.4	39.2	39.0
50	40.5	40.1	39.8	39.5	39.2	38.9	38.6	38.4	38.2
51	39.9	39.5	39.1	38.8	38.5	38.2	37.9	37.7	37.5
52	39.3	38.9	38.5	38.2	37.8	37.5	37.2	37.0	36.7
53	38.8	38.4	38.0	37.6	37.2	36.9	36.6	36.3	36.0
54	38.3	37.9	37.4	37.0	36.6	36.2	35.9	35.6	35.3
55	37.9	37.4	36.9	36.4	36.0	35.6	35.3	34.9	34.6
56	37.4	36.9	36.4	35.9	35.5	35.1	34.7	34.3	34.0
57	37.0	36.4	35.9	35.4	35.0	34.5	34.1	33.7	33.4
58	36.6	36.0	35.5	35.0	34.5	34.0	33.6	33.2	32.8
59	36.2	35.6	35.1	34.5	34.0	33.5	33.1	32.6	32.2
60	35.9	35.3	34.7	34.1	33.6	33.1	32.6	32.1	31.7
61	35.6	34.9	34.3	33.7	33.2	32.6	32.1	31.6	31.2
62	35.3	34.6	34.0	33.4	32.8	32.2	31.7	31.2	30.7
63	35.0	34.4	33.7	33.0	32.4	31.8	31.3	30.7	30.2
64	34.8	34.1	33.4	32.7	32.1	31.5	30.9	30.3	29.8
65	34.6	33.8	33.1	32.5	31.8	31.2	30.5	30.0	29.4
66	34.4	33.6	32.9	32.2	31.5	30.9	30.2	29.6	29.0
67	34.2	33.4	32.7	32.0	31.3	30.6	29.9	29.3	28.7
68	34.0	33.2	32.5	31.7	31.0	30.3	29.6	29.0	28.4
69	33.8	33.1	32.3	31.5	30.8	30.1	29.4	28.7	28.1
70	33.7	32.9	32.1	31.3	30.6	29.9	29.1	28.5	27.8
71	33.6	32.7	32.0	31.2	30.4	29.7	28.9	28.2	27.5
72	33.4	32.6	31.8	31.0	30.2	29.5	28.7	28.0	27.3
73	33.3	32.5	31.7	30.9	30.1	29.3	28.6	27.8	27.1
74	33.2	32.4	31.6	30.7	29.9	29.2	28.4	27.6	26.9
75	33.1	32.3	31.5	30.6	29.8	29.0	28.2	27.5	26.7

Ages	54	55	56	57	58	59	60	61	62
76	33.1	32.2	31.4	30.5	29.7	28.9	28.1	27.3	26.6
77	33.0	32.1	31.3	30.4	29.6	28.8	28.0	27.2	26.4
78	32.9	32.0	31.2	30.3	29.5	28.7	27.9	27.1	26.3
79	32.9	32.0	31.1	30.3	29.4	28.6	27.8	27.0	26.2
80	32.8	31.9	31.1	30.2	29.3	28.5	27.7	26.9	26.1
81	32.7	31.9	31.0	30.1	29.3	28.4	27.6	26.8	26.0
82	32.7	31.8	30.9	30.1	29.2	28.4	27.5	26.7	25.9
83	32.7	31.8	30.9	30.0	29.2	28.3	27.5	26.7	25.8
84	32.6	31.7	30.9	30.0	29.1	28.3	27.4	26.6	25.8
85	32.6	31.7	30.8	29.9	29.1	28.2	27.4	26.5	25.7
86	32.6	31.7	30.8	29.9	29.0	28.2	27.3	26.5	25.7
87	32.6	31.7	30.8	29.9	29.0	28.2	27.3	26.5	25.6
88	32.5	31.6	30.7	29.9	29.0	28.1	27.3	26.4	25.6
89	32.5	31.6	30.7	29.8	29.0	28.1	27.2	26.4	25.5
90	32.5	31.6	30.7	29.8	28.9	28.1	27.2	26.4	25.5
91	32.5	31.6	30.7	29.8	28.9	28.1	27.2	26.3	25.5
92	32.5	31.6	30.7	29.8	28.9	28.0	27.2	26.3	25.5
93	32.5	31.6	30.7	29.8	28.9	28.0	27.2	26.3	25.5
94	32.5	31.6	30.7	29.8	28.9	28.0	27.1	26.3	25.4
95	32.5	31.5	30.6	29.8	28.9	28.0	27.1	26.3	25.4
96	32.4	31.5	30.6	29.7	28.9	28.0	27.1	26.3	25.4
97	32.4	31.5	30.6	29.7	28.9	28.0	27.1	26.3	25.4
98	32.4	31.5	30.6	29.7	28.8	28.0	27.1	26.2	25.4
99	32.4	31.5	30.6	29.7	28.8	28.0	27.1	26.2	25.4
100	32.4	31.5	30.6	29.7	28.8	28.0	27.1	26.2	25.4
101	32.4	31.5	30.6	29.7	28.8	28.0	27.1	26.2	25.4
102	32.4	31.5	30.6	29.7	28.8	28.0	27.1	26.2	25.4
103	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
104	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
105	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
106	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
107	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
108	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
109	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
110	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
111	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
112	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
113	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
114	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
115	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.4
116	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.3
117	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.3
118	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.3
119	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.3
120+	32.4	31.5	30.6	29.7	28.8	27.9	27.1	26.2	25.3

Ages	63	64	65	66	67	68	69	70	71
0	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.8	83.8	83.8	83.7	83.7	83.7	83.7	83.7	83.7
2	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8	82.8
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.9	79.9	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.9	78.9	78.9	78.9	78.8	78.8	78.8	78.8	78.8
7	77.9	77.9	77.9	77.9	77.9	77.9	77.9	77.8	77.8
8	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9	75.9
10	75.0	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.9
11	74.0	74.0	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	73.0	73.0	73.0	73.0	72.9	72.9	72.9	72.9	72.9
13	72.0	72.0	72.0	72.0	72.0	72.0	71.9	71.9	71.9
14	71.0	71.0	71.0	71.0	71.0	71.0	71.0	71.0	70.9
15	70.1	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0
16	69.1	69.1	69.1	69.0	69.0	69.0	69.0	69.0	69.0
17	68.1	68.1	68.1	68.1	68.1	68.0	68.0	68.0	68.0
18	67.1	67.1	67.1	67.1	67.1	67.1	67.1	67.0	67.0
19	66.2	66.2	66.1	66.1	66.1	66.1	66.1	66.1	66.1
20	65.2	65.2	65.2	65.2	65.1	65.1	65.1	65.1	65.1
21	64.2	64.2	64.2	64.2	64.2	64.2	64.1	64.1	64.1
22	63.3	63.3	63.2	63.2	63.2	63.2	63.2	63.2	63.1
23	62.3	62.3	62.3	62.2	62.2	62.2	62.2	62.2	62.2
24	61.4	61.3	61.3	61.3	61.3	61.3	61.2	61.2	61.2

Ages	63	64	65	66	67	68	69	70	71
25	60.4	60.4	60.3	60.3	60.3	60.3	60.3	60.3	60.2
26	59.4	59.4	59.4	59.4	59.3	59.3	59.3	59.3	59.3
27	58.5	58.5	58.4	58.4	58.4	58.4	58.4	58.3	58.3
28	57.5	57.5	57.5	57.5	57.4	57.4	57.4	57.4	57.4
29	56.6	56.6	56.5	56.5	56.5	56.5	56.4	56.4	56.4
30	55.7	55.6	55.6	55.6	55.5	55.5	55.5	55.5	55.5
31	54.7	54.7	54.7	54.6	54.6	54.6	54.5	54.5	54.5
32	53.8	53.8	53.7	53.7	53.7	53.6	53.6	53.6	53.6
33	52.9	52.8	52.8	52.7	52.7	52.7	52.7	52.6	52.6
34	51.9	51.9	51.9	51.8	51.8	51.7	51.7	51.7	51.7
35	51.0	51.0	50.9	50.9	50.8	50.8	50.8	50.7	50.7
36	50.1	50.0	50.0	50.0	49.9	49.9	49.8	49.8	49.8
37	49.2	49.1	49.1	49.0	49.0	48.9	48.9	48.9	48.8
38	48.3	48.2	48.2	48.1	48.0	48.0	48.0	47.9	47.9
39	47.4	47.3	47.2	47.2	47.1	47.1	47.0	47.0	47.0
40	46.5	46.4	46.3	46.3	46.2	46.2	46.1	46.1	46.0
41	45.6	45.5	45.4	45.4	45.3	45.2	45.2	45.1	45.1
42	44.7	44.6	44.5	44.5	44.4	44.3	44.3	44.2	44.2
43	43.8	43.7	43.6	43.6	43.5	43.4	43.3	43.3	43.2
44	43.0	42.9	42.8	42.7	42.6	42.5	42.4	42.4	42.3
45	42.1	42.0	41.9	41.8	41.7	41.6	41.5	41.5	41.4
46	41.3	41.1	41.0	40.9	40.8	40.7	40.6	40.6	40.5
47	40.4	40.3	40.2	40.0	39.9	39.8	39.8	39.7	39.6
48	39.6	39.5	39.3	39.2	39.1	39.0	38.9	38.8	38.7
49	38.8	38.6	38.5	38.4	38.2	38.1	38.0	37.9	37.8
50	38.0	37.8	37.7	37.5	37.4	37.3	37.1	37.0	36.9
51	37.2	37.0	36.9	36.7	36.6	36.4	36.3	36.2	36.1
52	36.5	36.3	36.1	35.9	35.7	35.6	35.5	35.3	35.2
53	35.8	35.5	35.3	35.1	35.0	34.8	34.6	34.5	34.4
54	35.0	34.8	34.6	34.4	34.2	34.0	33.8	33.7	33.6
55	34.4	34.1	33.8	33.6	33.4	33.2	33.1	32.9	32.7
56	33.7	33.4	33.1	32.9	32.7	32.5	32.3	32.1	32.0
57	33.0	32.7	32.5	32.2	32.0	31.7	31.5	31.3	31.2
58	32.4	32.1	31.8	31.5	31.3	31.0	30.8	30.6	30.4
59	31.8	31.5	31.2	30.9	30.6	30.3	30.1	29.9	29.7
60	31.3	30.9	30.5	30.2	29.9	29.6	29.4	29.1	28.9
61	30.7	30.3	30.0	29.6	29.3	29.0	28.7	28.5	28.2
62	30.2	29.8	29.4	29.0	28.7	28.4	28.1	27.8	27.5
63	29.8	29.3	28.9	28.5	28.1	27.8	27.4	27.1	26.9
64	29.3	28.8	28.4	28.0	27.6	27.2	26.8	26.5	26.2
65	28.9	28.4	27.9	27.4	27.0	26.6	26.3	25.9	25.6
66	28.5	28.0	27.4	27.0	26.5	26.1	25.7	25.4	25.0
67	28.1	27.6	27.0	26.5	26.1	25.6	25.2	24.8	24.4
68	27.8	27.2	26.6	26.1	25.6	25.1	24.7	24.3	23.9
69	27.4	26.8	26.3	25.7	25.2	24.7	24.2	23.8	23.4
70	27.1	26.5	25.9	25.4	24.8	24.3	23.8	23.3	22.9
71	26.9	26.2	25.6	25.0	24.4	23.9	23.4	22.9	22.4
72	26.6	26.0	25.3	24.7	24.1	23.5	23.0	22.5	22.0
73	26.4	25.7	25.0	24.4	23.8	23.2	22.6	22.1	21.6
74	26.2	25.5	24.8	24.1	23.5	22.9	22.3	21.7	21.2
75	26.0	25.3	24.6	23.9	23.2	22.6	22.0	21.4	20.8
76	25.8	25.1	24.4	23.7	23.0	22.4	21.7	21.1	20.5
77	25.7	24.9	24.2	23.5	22.8	22.1	21.5	20.8	20.2
78	25.5	24.8	24.0	23.3	22.6	21.9	21.2	20.6	20.0
79	25.4	24.6	23.9	23.2	22.4	21.7	21.0	20.4	19.7
80	25.3	24.5	23.8	23.0	22.3	21.6	20.9	20.2	19.5
81	25.2	24.4	23.6	22.9	22.1	21.4	20.7	20.0	19.3
82	25.1	24.3	23.5	22.8	22.0	21.3	20.5	19.8	19.1
83	25.0	24.2	23.4	22.7	21.9	21.2	20.4	19.7	19.0
84	25.0	24.2	23.4	22.6	21.8	21.0	20.3	19.6	18.8
85	24.9	24.1	23.3	22.5	21.7	21.0	20.2	19.4	18.7
86	24.8	24.0	23.2	22.4	21.7	20.9	20.1	19.3	18.6
87	24.8	24.0	23.2	22.4	21.6	20.8	20.0	19.3	18.5
88	24.8	23.9	23.1	22.3	21.5	20.7	20.0	19.2	18.4
89	24.7	23.9	23.1	22.3	21.5	20.7	19.9	19.1	18.4
90	24.7	23.9	23.0	22.2	21.4	20.6	19.9	19.1	18.3
91	24.7	23.8	23.0	22.2	21.4	20.6	19.8	19.0	18.3
92	24.6	23.8	23.0	22.2	21.4	20.6	19.8	19.0	18.2
93	24.6	23.8	23.0	22.2	21.3	20.5	19.7	18.9	18.2
94	24.6	23.8	22.9	22.1	21.3	20.5	19.7	18.9	18.1
95	24.6	23.8	22.9	22.1	21.3	20.5	19.7	18.9	18.1
96	24.6	23.7	22.9	22.1	21.3	20.5	19.7	18.9	18.1
97	24.6	23.7	22.9	22.1	21.3	20.5	19.7	18.9	18.1
98	24.6	23.7	22.9	22.1	21.3	20.4	19.6	18.8	18.0

Ages	63	64	65	66	67	68	69	70	71
99	24.5	23.7	22.9	22.1	21.2	20.4	19.6	18.8	18.0
100	24.5	23.7	22.9	22.1	21.2	20.4	19.6	18.8	18.0
101	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0
102	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0
103	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0
104	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0
105	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0
106	24.5	23.7	22.9	22.0	21.2	20.4	19.6	18.8	18.0
107	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
108	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
109	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
110	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
111	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
112	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
113	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
114	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
115	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
116	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.8	18.0
117	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.7	17.9
118	24.5	23.7	22.8	22.0	21.2	20.4	19.6	18.7	17.9
119	24.5	23.6	22.8	22.0	21.2	20.4	19.5	18.7	17.9
120+	24.5	23.6	22.8	22.0	21.2	20.4	19.5	18.7	17.9

Ages	72	73	74	75	76	77	78	79	80
0	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6	84.6
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.8	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7
3	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8	81.8
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8
8	76.9	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8
9	75.9	75.9	75.9	75.9	75.8	75.8	75.8	75.8	75.8
10	74.9	74.9	74.9	74.9	74.9	74.9	74.9	74.8	74.8
11	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9	73.9
12	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	70.0	70.0	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	69.0	69.0	69.0	69.0	68.9	68.9	68.9	68.9	68.9
17	68.0	68.0	68.0	68.0	68.0	68.0	68.0	68.0	67.9
18	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0	67.0
19	66.1	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.1	65.1	65.1	65.0	65.0	65.0	65.0	65.0	65.0
21	64.1	64.1	64.1	64.1	64.1	64.1	64.1	64.0	64.0
22	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1	63.1
23	62.2	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1
24	61.2	61.2	61.2	61.2	61.2	61.1	61.1	61.1	61.1
25	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2	60.2
26	59.3	59.3	59.2	59.2	59.2	59.2	59.2	59.2	59.2
27	58.3	58.3	58.3	58.3	58.3	58.2	58.2	58.2	58.2
28	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3	57.3
29	56.4	56.4	56.4	56.3	56.3	56.3	56.3	56.3	56.3
30	55.4	55.4	55.4	55.4	55.4	55.4	55.4	55.4	55.3
31	54.5	54.5	54.5	54.4	54.4	54.4	54.4	54.4	54.4
32	53.5	53.5	53.5	53.5	53.5	53.5	53.4	53.4	53.4
33	52.6	52.6	52.5	52.5	52.5	52.5	52.5	52.5	52.5
34	51.6	51.6	51.6	51.6	51.6	51.6	51.5	51.5	51.5
35	50.7	50.7	50.6	50.6	50.6	50.6	50.6	50.6	50.6
36	49.7	49.7	49.7	49.7	49.7	49.6	49.6	49.6	49.6
37	48.8	48.8	48.8	48.7	48.7	48.7	48.7	48.7	48.7
38	47.9	47.8	47.8	47.8	47.8	47.7	47.7	47.7	47.7
39	46.9	46.9	46.9	46.8	46.8	46.8	46.8	46.8	46.7
40	46.0	45.9	45.9	45.9	45.9	45.8	45.8	45.8	45.8
41	45.0	45.0	45.0	44.9	44.9	44.9	44.9	44.9	44.8
42	44.1	44.1	44.0	44.0	44.0	43.9	43.9	43.9	43.9
43	43.2	43.1	43.1	43.1	43.0	43.0	43.0	43.0	42.9
44	42.3	42.2	42.2	42.1	42.1	42.1	42.0	42.0	42.0
45	41.3	41.3	41.2	41.2	41.2	41.1	41.1	41.1	41.1
46	40.4	40.4	40.3	40.3	40.2	40.2	40.2	40.1	40.1
47	39.5	39.5	39.4	39.4	39.3	39.3	39.2	39.2	39.2

Ages	72	73	74	75	76	77	78	79	80
48	38.6	38.6	38.5	38.4	38.4	38.4	38.3	38.3	38.2
49	37.7	37.7	37.6	37.5	37.5	37.4	37.4	37.4	37.3
50	36.9	36.8	36.7	36.6	36.6	36.5	36.5	36.4	36.4
51	36.0	35.9	35.8	35.7	35.7	35.6	35.6	35.5	35.5
52	35.1	35.0	34.9	34.9	34.8	34.7	34.7	34.6	34.6
53	34.3	34.2	34.1	34.0	33.9	33.9	33.8	33.7	33.7
54	33.4	33.3	33.2	33.1	33.1	33.0	32.9	32.9	32.8
55	32.6	32.5	32.4	32.3	32.2	32.1	32.0	32.0	31.9
56	31.8	31.7	31.6	31.5	31.4	31.3	31.2	31.1	31.1
57	31.0	30.9	30.7	30.6	30.5	30.4	30.3	30.3	30.2
58	30.2	30.1	29.9	29.8	29.7	29.6	29.5	29.4	29.3
59	29.5	29.3	29.2	29.0	28.9	28.8	28.7	28.6	28.5
60	28.7	28.6	28.4	28.2	28.1	28.0	27.9	27.8	27.7
61	28.0	27.8	27.6	27.5	27.3	27.2	27.1	27.0	26.9
62	27.3	27.1	26.9	26.7	26.6	26.4	26.3	26.2	26.1
63	26.6	26.4	26.2	26.0	25.8	25.7	25.5	25.4	25.3
64	26.0	25.7	25.5	25.3	25.1	24.9	24.8	24.6	24.5
65	25.3	25.0	24.8	24.6	24.4	24.2	24.0	23.9	23.8
66	24.7	24.4	24.1	23.9	23.7	23.5	23.3	23.2	23.0
67	24.1	23.8	23.5	23.2	23.0	22.8	22.6	22.4	22.3
68	23.5	23.2	22.9	22.6	22.4	22.1	21.9	21.7	21.6
69	23.0	22.6	22.3	22.0	21.7	21.5	21.2	21.0	20.9
70	22.5	22.1	21.7	21.4	21.1	20.8	20.6	20.4	20.2
71	22.0	21.6	21.2	20.8	20.5	20.2	20.0	19.7	19.5
72	21.5	21.1	20.7	20.3	20.0	19.6	19.4	19.1	18.9
73	21.1	20.6	20.2	19.8	19.4	19.1	18.8	18.5	18.2
74	20.7	20.2	19.7	19.3	18.9	18.6	18.2	17.9	17.6
75	20.3	19.8	19.3	18.9	18.5	18.1	17.7	17.4	17.1
76	20.0	19.4	18.9	18.5	18.0	17.6	17.2	16.9	16.5
77	19.6	19.1	18.6	18.1	17.6	17.2	16.8	16.4	16.0
78	19.4	18.8	18.2	17.7	17.2	16.8	16.3	15.9	15.6
79	19.1	18.5	17.9	17.4	16.9	16.4	15.9	15.5	15.1
80	18.9	18.2	17.6	17.1	16.5	16.0	15.6	15.1	14.7
81	18.6	18.0	17.4	16.8	16.2	15.7	15.2	14.7	14.3
82	18.4	17.8	17.2	16.6	16.0	15.4	14.9	14.4	14.0
83	18.3	17.6	17.0	16.3	15.7	15.2	14.6	14.1	13.6
84	18.1	17.4	16.8	16.1	15.5	14.9	14.4	13.8	13.3
85	18.0	17.3	16.6	16.0	15.3	14.7	14.1	13.6	13.1
86	17.9	17.2	16.5	15.8	15.2	14.5	13.9	13.4	12.8
87	17.8	17.1	16.4	15.7	15.0	14.4	13.8	13.2	12.6
88	17.7	17.0	16.2	15.6	14.9	14.2	13.6	13.0	12.4
89	17.6	16.9	16.2	15.4	14.8	14.1	13.5	12.9	12.3
90	17.5	16.8	16.1	15.4	14.7	14.0	13.4	12.7	12.1
91	17.5	16.7	16.0	15.3	14.6	13.9	13.2	12.6	12.0
92	17.4	16.7	15.9	15.2	14.5	13.8	13.2	12.5	11.9
93	17.4	16.6	15.9	15.2	14.4	13.7	13.1	12.4	11.8
94	17.4	16.6	15.8	15.1	14.4	13.7	13.0	12.4	11.7
95	17.3	16.6	15.8	15.1	14.3	13.6	12.9	12.3	11.6
96	17.3	16.5	15.8	15.0	14.3	13.6	12.9	12.2	11.6
97	17.3	16.5	15.7	15.0	14.3	13.5	12.9	12.2	11.5
98	17.3	16.5	15.7	15.0	14.2	13.5	12.8	12.1	11.5
99	17.2	16.5	15.7	14.9	14.2	13.5	12.8	12.1	11.4
100	17.2	16.4	15.7	14.9	14.2	13.5	12.8	12.1	11.4
101	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.4
102	17.2	16.4	15.7	14.9	14.2	13.4	12.7	12.0	11.4
103	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
104	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
105	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
106	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
107	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
108	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
109	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
110	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
111	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
112	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
113	17.2	16.4	15.6	14.9	14.1	13.4	12.7	12.0	11.3
114	17.2	16.4	15.6	14.8	14.1	13.4	12.6	12.0	11.3
115	17.2	16.4	15.6	14.8	14.1	13.4	12.6	11.9	11.3
116	17.2	16.4	15.6	14.8	14.1	13.3	12.6	11.9	11.3
117	17.1	16.4	15.6	14.8	14.1	13.3	12.6	11.9	11.2
118	17.1	16.4	15.6	14.8	14.1	13.3	12.6	11.9	11.2
119	17.1	16.3	15.6	14.8	14.0	13.3	12.6	11.9	11.2
120+	17.1	16.3	15.6	14.8	14.0	13.3	12.6	11.9	11.2

Ages	81	82	83	84	85	86	87	88	89
0	84.6	84.6	84.6	84.6	84.6	84.5	84.5	84.5	84.5
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7
3	81.8	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8
8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8
9	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8
10	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8
11	73.9	73.9	73.9	73.8	73.8	73.8	73.8	73.8	73.8
12	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9	72.9
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9
17	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9
18	67.0	67.0	67.0	67.0	67.0	67.0	66.9	66.9	66.9
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0
22	63.1	63.1	63.0	63.0	63.0	63.0	63.0	63.0	63.0
23	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1	62.1
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1
26	59.2	59.2	59.2	59.2	59.2	59.2	59.1	59.1	59.1
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.3	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2
29	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3	56.3
30	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.4	54.4	54.4	54.4	54.4	54.3	54.3	54.3	54.3
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.5	52.5	52.5	52.4	52.4	52.4	52.4	52.4	52.4
34	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5
35	50.6	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5
36	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6	49.6
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.7	47.7	47.7	47.7	47.7	47.6	47.6	47.6	47.6
39	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
40	45.8	45.8	45.8	45.7	45.7	45.7	45.7	45.7	45.7
41	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8	44.8
42	43.9	43.9	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.9	42.9	42.9	42.9	42.9	42.9	42.9	42.8	42.8
44	42.0	42.0	41.9	41.9	41.9	41.9	41.9	41.9	41.9
45	41.0	41.0	41.0	41.0	41.0	41.0	40.9	40.9	40.9
46	40.1	40.1	40.0	40.0	40.0	40.0	40.0	40.0	40.0
47	39.1	39.1	39.1	39.1	39.1	39.1	39.0	39.0	39.0
48	38.2	38.2	38.2	38.1	38.1	38.1	38.1	38.1	38.1
49	37.3	37.3	37.2	37.2	37.2	37.2	37.2	37.1	37.1
50	36.4	36.3	36.3	36.3	36.3	36.2	36.2	36.2	36.2
51	35.4	35.4	35.4	35.4	35.3	35.3	35.3	35.3	35.3
52	34.5	34.5	34.5	34.4	34.4	34.4	34.4	34.4	34.3
53	33.6	33.6	33.6	33.5	33.5	33.5	33.5	33.4	33.4
54	32.7	32.7	32.7	32.6	32.6	32.6	32.6	32.5	32.5
55	31.9	31.8	31.8	31.7	31.7	31.7	31.7	31.6	31.6
56	31.0	30.9	30.9	30.9	30.8	30.8	30.8	30.7	30.7
57	30.1	30.1	30.0	30.0	29.9	29.9	29.9	29.9	29.8
58	29.3	29.2	29.2	29.1	29.1	29.0	29.0	29.0	29.0
59	28.4	28.4	28.3	28.3	28.2	28.2	28.2	28.1	28.1
60	27.6	27.5	27.5	27.4	27.4	27.3	27.3	27.3	27.2
61	26.8	26.7	26.7	26.6	26.5	26.5	26.5	26.4	26.4
62	26.0	25.9	25.8	25.8	25.7	25.7	25.6	25.6	25.5
63	25.2	25.1	25.0	25.0	24.9	24.8	24.8	24.8	24.7
64	24.4	24.3	24.2	24.2	24.1	24.0	24.0	23.9	23.9
65	23.6	23.5	23.4	23.4	23.3	23.2	23.2	23.1	23.1
66	22.9	22.8	22.7	22.6	22.5	22.4	22.4	22.3	22.3
67	22.1	22.0	21.9	21.8	21.7	21.7	21.6	21.5	21.5
68	21.4	21.3	21.2	21.0	21.0	20.9	20.8	20.7	20.7
69	20.7	20.5	20.4	20.3	20.2	20.1	20.0	20.0	19.9
70	20.0	19.8	19.7	19.6	19.4	19.3	19.3	19.2	19.1
71	19.3	19.1	19.0	18.8	18.7	18.6	18.5	18.4	18.4
72	18.6	18.4	18.3	18.1	18.0	17.9	17.8	17.7	17.6
73	18.0	17.8	17.6	17.4	17.3	17.2	17.1	17.0	16.9

Ages	81	82	83	84	85	86	87	88	89
74	17.4	17.2	17.0	16.8	16.6	16.5	16.4	16.2	16.2
75	16.8	16.6	16.3	16.1	16.0	15.8	15.7	15.6	15.4
76	16.2	16.0	15.7	15.5	15.3	15.2	15.0	14.9	14.8
77	15.7	15.4	15.2	14.9	14.7	14.5	14.4	14.2	14.1
78	15.2	14.9	14.6	14.4	14.1	13.9	13.8	13.6	13.5
79	14.7	14.4	14.1	13.8	13.6	13.4	13.2	13.0	12.9
80	14.3	14.0	13.6	13.3	13.1	12.8	12.6	12.4	12.3
81	13.9	13.5	13.2	12.9	12.6	12.3	12.1	11.9	11.7
82	13.5	13.1	12.8	12.4	12.1	11.9	11.6	11.4	11.2
83	13.2	12.8	12.4	12.0	11.7	11.4	11.2	10.9	10.7
84	12.9	12.4	12.0	11.7	11.3	11.0	10.7	10.5	10.3
85	12.6	12.1	11.7	11.3	11.0	10.7	10.4	10.1	9.9
86	12.3	11.9	11.4	11.0	10.7	10.3	10.0	9.7	9.5
87	12.1	11.6	11.2	10.7	10.4	10.0	9.7	9.4	9.1
88	11.9	11.4	10.9	10.5	10.1	9.7	9.4	9.1	8.8
89	11.7	11.2	10.7	10.3	9.9	9.5	9.1	8.8	8.5
90	11.6	11.0	10.5	10.1	9.6	9.2	8.9	8.5	8.2
91	11.4	10.9	10.4	9.9	9.5	9.0	8.7	8.3	8.0
92	11.3	10.8	10.2	9.7	9.3	8.9	8.5	8.1	7.8
93	11.2	10.6	10.1	9.6	9.1	8.7	8.3	7.9	7.6
94	11.1	10.5	10.0	9.5	9.0	8.6	8.1	7.7	7.4
95	11.0	10.5	9.9	9.4	8.9	8.4	8.0	7.6	7.2
96	11.0	10.4	9.8	9.3	8.8	8.3	7.9	7.5	7.1
97	10.9	10.3	9.7	9.2	8.7	8.2	7.8	7.4	7.0
98	10.9	10.3	9.7	9.1	8.6	8.1	7.7	7.3	6.9
99	10.8	10.2	9.6	9.1	8.6	8.1	7.6	7.2	6.8
100	10.8	10.2	9.6	9.0	8.5	8.0	7.6	7.1	6.7
101	10.7	10.1	9.5	9.0	8.5	8.0	7.5	7.1	6.7
102	10.7	10.1	9.5	8.9	8.4	7.9	7.4	7.0	6.6
103	10.7	10.1	9.5	8.9	8.4	7.9	7.4	7.0	6.6
104	10.7	10.1	9.5	8.9	8.4	7.9	7.4	6.9	6.5
105	10.7	10.0	9.5	8.9	8.3	7.8	7.4	6.9	6.5
106	10.7	10.0	9.4	8.9	8.3	7.8	7.4	6.9	6.5
107	10.7	10.0	9.4	8.9	8.3	7.8	7.3	6.9	6.5
108	10.7	10.0	9.4	8.9	8.3	7.8	7.3	6.9	6.5
109	10.7	10.0	9.4	8.9	8.3	7.8	7.3	6.9	6.5
110	10.7	10.0	9.4	8.9	8.3	7.8	7.3	6.9	6.5
111	10.6	10.0	9.4	8.8	8.3	7.8	7.3	6.9	6.4
112	10.6	10.0	9.4	8.8	8.3	7.8	7.3	6.9	6.4
113	10.6	10.0	9.4	8.8	8.3	7.8	7.3	6.8	6.4
114	10.6	10.0	9.4	8.8	8.3	7.8	7.3	6.8	6.4
115	10.6	10.0	9.4	8.8	8.3	7.7	7.3	6.8	6.4
116	10.6	10.0	9.4	8.8	8.2	7.7	7.2	6.8	6.3
117	10.6	9.9	9.3	8.7	8.2	7.7	7.2	6.7	6.3
118	10.5	9.9	9.3	8.7	8.2	7.6	7.1	6.7	6.2
119	10.5	9.9	9.3	8.7	8.1	7.6	7.1	6.6	6.2
120+	10.5	9.9	9.2	8.6	8.1	7.5	7.0	6.6	6.1

Ages	90	91	92	93	94	95	96	97	98
0	84.5	84.5	84.5	84.5	84.5	84.5	84.5	84.5	84.5
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7
3	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8
8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8
9	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8
10	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8
11	73.8	73.8	73.8	73.8	73.8	73.8	73.8	73.8	73.8
12	72.9	72.9	72.9	72.8	72.8	72.8	72.8	72.8	72.8
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9
17	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9
18	66.9	66.9	66.9	66.9	66.9	66.9	66.9	66.9	66.9
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0
22	63.0	63.0	63.0	63.0	63.0	63.0	63.0	63.0	63.0

Ages	90	91	92	93	94	95	96	97	98
23	62.1	62.1	62.0	62.0	62.0	62.0	62.0	62.0	62.0
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1
26	59.1	59.1	59.1	59.1	59.1	59.1	59.1	59.1	59.1
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2
29	56.3	56.3	56.2	56.2	56.2	56.2	56.2	56.2	56.2
30	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.3	54.3	54.3	54.3	54.3	54.3	54.3	54.3	54.3
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.4	52.4	52.4	52.4	52.4	52.4	52.4	52.4	52.4
34	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5	51.5
35	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5
36	49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6
39	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
40	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7
41	44.8	44.7	44.7	44.7	44.7	44.7	44.7	44.7	44.7
42	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.8	42.8	42.8	42.8	42.8	42.8	42.8	42.8	42.8
44	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9
45	40.9	40.9	40.9	40.9	40.9	40.9	40.9	40.9	40.9
46	40.0	40.0	40.0	40.0	40.0	40.0	39.9	39.9	39.9
47	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0
48	38.1	38.1	38.1	38.1	38.1	38.0	38.0	38.0	38.0
49	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1
50	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.2	36.1
51	35.3	35.2	35.2	35.2	35.2	35.2	35.2	35.2	35.2
52	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3
53	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4	33.4
54	32.5	32.5	32.5	32.5	32.5	32.5	32.4	32.4	32.4
55	31.6	31.6	31.6	31.6	31.6	31.5	31.5	31.5	31.5
56	30.7	30.7	30.7	30.7	30.7	30.6	30.6	30.6	30.6
57	29.8	29.8	29.8	29.8	29.8	29.8	29.7	29.7	29.7
58	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.9	28.8
59	28.1	28.1	28.0	28.0	28.0	28.0	28.0	28.0	28.0
60	27.2	27.2	27.2	27.2	27.1	27.1	27.1	27.1	27.1
61	26.4	26.3	26.3	26.3	26.3	26.3	26.3	26.3	26.2
62	25.5	25.5	25.5	25.5	25.4	25.4	25.4	25.4	25.4
63	24.7	24.7	24.6	24.6	24.6	24.6	24.6	24.6	24.6
64	23.9	23.8	23.8	23.8	23.8	23.8	23.7	23.7	23.7
65	23.0	23.0	23.0	23.0	22.9	22.9	22.9	22.9	22.9
66	22.2	22.2	22.2	22.2	22.1	22.1	22.1	22.1	22.1
67	21.4	21.4	21.4	21.3	21.3	21.3	21.3	21.3	21.3
68	20.6	20.6	20.6	20.5	20.5	20.5	20.5	20.5	20.4
69	19.9	19.8	19.8	19.7	19.7	19.7	19.7	19.7	19.6
70	19.1	19.0	19.0	18.9	18.9	18.9	18.9	18.9	18.8
71	18.3	18.3	18.2	18.2	18.1	18.1	18.1	18.1	18.0
72	17.5	17.5	17.4	17.4	17.4	17.3	17.3	17.3	17.3
73	16.8	16.7	16.7	16.6	16.6	16.6	16.5	16.5	16.5
74	16.1	16.0	15.9	15.9	15.8	15.8	15.8	15.7	15.7
75	15.4	15.3	15.2	15.2	15.1	15.1	15.0	15.0	15.0
76	14.7	14.6	14.5	14.4	14.4	14.3	14.3	14.3	14.2
77	14.0	13.9	13.8	13.7	13.7	13.6	13.6	13.5	13.5
78	13.4	13.2	13.2	13.1	13.0	12.9	12.9	12.9	12.8
79	12.7	12.6	12.5	12.4	12.4	12.3	12.2	12.2	12.1
80	12.1	12.0	11.9	11.8	11.7	11.6	11.6	11.5	11.5
81	11.6	11.4	11.3	11.2	11.1	11.0	11.0	10.9	10.9
82	11.0	10.9	10.8	10.6	10.5	10.5	10.4	10.3	10.3
83	10.5	10.4	10.2	10.1	10.0	9.9	9.8	9.7	9.7
84	10.1	9.9	9.7	9.6	9.5	9.4	9.3	9.2	9.1
85	9.6	9.5	9.3	9.1	9.0	8.9	8.8	8.7	8.6
86	9.2	9.0	8.9	8.7	8.6	8.4	8.3	8.2	8.1
87	8.9	8.7	8.5	8.3	8.1	8.0	7.9	7.8	7.7
88	8.5	8.3	8.1	7.9	7.7	7.6	7.5	7.4	7.3
89	8.2	8.0	7.8	7.6	7.4	7.2	7.1	7.0	6.9
90	7.9	7.7	7.5	7.3	7.1	6.9	6.8	6.6	6.5
91	7.7	7.4	7.2	7.0	6.8	6.6	6.5	6.3	6.2
92	7.5	7.2	6.9	6.7	6.5	6.3	6.2	6.0	5.9
93	7.3	7.0	6.7	6.5	6.3	6.1	5.9	5.8	5.6
94	7.1	6.8	6.5	6.3	6.0	5.8	5.7	5.5	5.4
95	6.9	6.6	6.3	6.1	5.8	5.6	5.5	5.3	5.1
96	6.8	6.5	6.2	5.9	5.7	5.5	5.3	5.1	4.9

Ages	90	91	92	93	94	95	96	97	98
97	6.6	6.3	6.0	5.8	5.5	5.3	5.1	4.9	4.8
98	6.5	6.2	5.9	5.6	5.4	5.1	4.9	4.8	4.6
99	6.4	6.1	5.8	5.5	5.3	5.0	4.8	4.6	4.5
100	6.4	6.0	5.7	5.4	5.1	4.9	4.7	4.5	4.3
101	6.3	5.9	5.6	5.3	5.1	4.8	4.6	4.4	4.2
102	6.2	5.9	5.6	5.3	5.0	4.7	4.5	4.3	4.1
103	6.2	5.8	5.5	5.2	4.9	4.7	4.4	4.2	4.0
104	6.1	5.8	5.5	5.1	4.9	4.6	4.4	4.2	4.0
105	6.1	5.8	5.4	5.1	4.8	4.6	4.3	4.1	3.9
106	6.1	5.7	5.4	5.1	4.8	4.6	4.3	4.1	3.9
107	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
108	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
109	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
110	6.1	5.7	5.4	5.1	4.8	4.5	4.3	4.1	3.9
111	6.1	5.7	5.4	5.0	4.8	4.5	4.3	4.0	3.9
112	6.0	5.7	5.3	5.0	4.7	4.5	4.2	4.0	3.8
113	6.0	5.7	5.3	5.0	4.7	4.5	4.2	4.0	3.8
114	6.0	5.6	5.3	5.0	4.7	4.4	4.2	4.0	3.8
115	6.0	5.6	5.3	5.0	4.7	4.4	4.2	3.9	3.7
116	5.9	5.6	5.2	4.9	4.6	4.3	4.1	3.9	3.7
117	5.9	5.5	5.2	4.8	4.5	4.3	4.0	3.8	3.6
118	5.8	5.4	5.1	4.8	4.4	4.2	3.9	3.7	3.5
119	5.7	5.4	5.0	4.7	4.3	4.0	3.8	3.5	3.3
120+	5.7	5.3	4.9	4.6	4.2	3.9	3.7	3.4	3.2

Ages	99	100	101	102	103	104	105	106	107
0	84.5	84.5	84.5	84.5	84.5	84.5	84.5	84.5	84.5
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7
3	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8
8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8
9	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8
10	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8
11	73.8	73.8	73.8	73.8	73.8	73.8	73.8	73.8	73.8
12	72.8	72.8	72.8	72.8	72.8	72.8	72.8	72.8	72.8
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9
17	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9
18	66.9	66.9	66.9	66.9	66.9	66.9	66.9	66.9	66.9
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0
22	63.0	63.0	63.0	63.0	63.0	63.0	63.0	63.0	63.0
23	62.0	62.0	62.0	62.0	62.0	62.0	62.0	62.0	62.0
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1
26	59.1	59.1	59.1	59.1	59.1	59.1	59.1	59.1	59.1
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2
29	56.2	56.2	56.2	56.2	56.2	56.2	56.2	56.2	56.2
30	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.3	54.3	54.3	54.3	54.3	54.3	54.3	54.3	54.3
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.4	52.4	52.4	52.4	52.4	52.4	52.4	52.4	52.4
34	51.5	51.5	51.4	51.4	51.4	51.4	51.4	51.4	51.4
35	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5
36	49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6
39	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7	46.7
40	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7
41	44.7	44.7	44.7	44.7	44.7	44.7	44.7	44.7	44.7
42	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.8	42.8	42.8	42.8	42.8	42.8	42.8	42.8	42.8
44	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9
45	40.9	40.9	40.9	40.9	40.9	40.9	40.9	40.9	40.9

Ages	99	100	101	102	103	104	105	106	107
46	39.9	39.9	39.9	39.9	39.9	39.9	39.9	39.9	39.9
47	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0
48	38.0	38.0	38.0	38.0	38.0	38.0	38.0	38.0	38.0
49	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1
50	36.1	36.1	36.1	36.1	36.1	36.1	36.1	36.1	36.1
51	35.2	35.2	35.2	35.2	35.2	35.2	35.2	35.2	35.2
52	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3
53	33.3	33.3	33.3	33.3	33.3	33.3	33.3	33.3	33.3
54	32.4	32.4	32.4	32.4	32.4	32.4	32.4	32.4	32.4
55	31.5	31.5	31.5	31.5	31.5	31.5	31.5	31.5	31.5
56	30.6	30.6	30.6	30.6	30.6	30.6	30.6	30.6	30.6
57	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7
58	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8
59	28.0	28.0	28.0	28.0	27.9	27.9	27.9	27.9	27.9
60	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1
61	26.2	26.2	26.2	26.2	26.2	26.2	26.2	26.2	26.2
62	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4
63	24.5	24.5	24.5	24.5	24.5	24.5	24.5	24.5	24.5
64	23.7	23.7	23.7	23.7	23.7	23.7	23.7	23.7	23.7
65	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.9	22.8
66	22.1	22.1	22.0	22.0	22.0	22.0	22.0	22.0	22.0
67	21.2	21.2	21.2	21.2	21.2	21.2	21.2	21.2	21.2
68	20.4	20.4	20.4	20.4	20.4	20.4	20.4	20.4	20.4
69	19.6	19.6	19.6	19.6	19.6	19.6	19.6	19.6	19.6
70	18.8	18.8	18.8	18.8	18.8	18.8	18.8	18.8	18.8
71	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0
72	17.2	17.2	17.2	17.2	17.2	17.2	17.2	17.2	17.2
73	16.5	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4
74	15.7	15.7	15.7	15.7	15.6	15.6	15.6	15.6	15.6
75	14.9	14.9	14.9	14.9	14.9	14.9	14.9	14.9	14.9
76	14.2	14.2	14.2	14.2	14.1	14.1	14.1	14.1	14.1
77	13.5	13.5	13.4	13.4	13.4	13.4	13.4	13.4	13.4
78	12.8	12.8	12.7	12.7	12.7	12.7	12.7	12.7	12.7
79	12.1	12.1	12.0	12.0	12.0	12.0	12.0	12.0	12.0
80	11.4	11.4	11.4	11.4	11.3	11.3	11.3	11.3	11.3
81	10.8	10.8	10.7	10.7	10.7	10.7	10.7	10.7	10.7
82	10.2	10.2	10.1	10.1	10.1	10.1	10.0	10.0	10.0
83	9.6	9.6	9.5	9.5	9.5	9.5	9.5	9.4	9.4
84	9.1	9.0	9.0	8.9	8.9	8.9	8.9	8.9	8.9
85	8.6	8.5	8.5	8.4	8.4	8.4	8.3	8.3	8.3
86	8.1	8.0	8.0	7.9	7.9	7.9	7.8	7.8	7.8
87	7.6	7.6	7.5	7.4	7.4	7.4	7.4	7.4	7.3
88	7.2	7.1	7.1	7.0	7.0	6.9	6.9	6.9	6.9
89	6.8	6.7	6.7	6.6	6.6	6.5	6.5	6.5	6.5
90	6.4	6.4	6.3	6.2	6.2	6.1	6.1	6.1	6.1
91	6.1	6.0	5.9	5.9	5.8	5.8	5.8	5.7	5.7
92	5.8	5.7	5.6	5.6	5.5	5.5	5.4	5.4	5.4
93	5.5	5.4	5.3	5.3	5.2	5.1	5.1	5.1	5.1
94	5.3	5.1	5.1	5.0	4.9	4.9	4.8	4.8	4.8
95	5.0	4.9	4.8	4.7	4.7	4.6	4.6	4.6	4.5
96	4.8	4.7	4.6	4.5	4.4	4.4	4.3	4.3	4.3
97	4.6	4.5	4.4	4.3	4.2	4.2	4.1	4.1	4.1
98	4.5	4.3	4.2	4.1	4.0	4.0	3.9	3.9	3.9
99	4.3	4.2	4.1	4.0	3.9	3.8	3.8	3.7	3.7
100	4.2	4.0	3.9	3.8	3.7	3.7	3.6	3.6	3.6
101	4.1	3.9	3.8	3.7	3.6	3.5	3.5	3.5	3.4
102	4.0	3.8	3.7	3.6	3.5	3.4	3.4	3.3	3.3
103	3.9	3.7	3.6	3.5	3.4	3.3	3.3	3.2	3.2
104	3.8	3.7	3.5	3.4	3.3	3.2	3.2	3.2	3.1
105	3.8	3.6	3.5	3.4	3.3	3.2	3.1	3.1	3.1
106	3.7	3.6	3.5	3.3	3.2	3.2	3.1	3.1	3.1
107	3.7	3.6	3.4	3.3	3.2	3.1	3.1	3.1	3.0
108	3.7	3.6	3.4	3.3	3.2	3.1	3.1	3.0	3.0
109	3.7	3.5	3.4	3.3	3.2	3.1	3.1	3.0	3.0
110	3.7	3.5	3.4	3.3	3.2	3.1	3.0	3.0	3.0
111	3.7	3.5	3.4	3.3	3.2	3.1	3.0	3.0	3.0
112	3.7	3.5	3.4	3.2	3.1	3.1	3.0	3.0	3.0
113	3.6	3.5	3.3	3.2	3.1	3.0	3.0	3.0	2.9
114	3.6	3.4	3.3	3.2	3.1	3.0	3.0	2.9	2.9
115	3.6	3.4	3.3	3.1	3.0	3.0	2.9	2.9	2.9
116	3.5	3.3	3.2	3.1	3.0	2.9	2.8	2.8	2.8
117	3.4	3.2	3.1	3.0	2.9	2.8	2.7	2.7	2.7
118	3.3	3.1	3.0	2.8	2.7	2.6	2.6	2.5	2.5
119	3.1	2.9	2.8	2.6	2.5	2.4	2.3	2.3	2.3

Ages	99	100	101	102	103	104	105	106	107
120+	3.0	2.8	2.6	2.5	2.3	2.2	2.1	2.1	2.1

Ages	108	109	110	111	112	113	114	115	116
0	84.5	84.5	84.5	84.5	84.5	84.5	84.5	84.5	84.5
1	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7	83.7
2	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7	82.7
3	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7	81.7
4	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8	78.8
7	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8	77.8
8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8	76.8
9	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8	75.8
10	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8	74.8
11	73.8	73.8	73.8	73.8	73.8	73.8	73.8	73.8	73.8
12	72.8	72.8	72.8	72.8	72.8	72.8	72.8	72.8	72.8
13	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9	69.9
16	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9	68.9
17	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9	67.9
18	66.9	66.9	66.9	66.9	66.9	66.9	66.9	66.9	66.9
19	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0	65.0
21	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0	64.0
22	63.0	63.0	63.0	63.0	63.0	63.0	63.0	63.0	63.0
23	62.0	62.0	62.0	62.0	62.0	62.0	62.0	62.0	62.0
24	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1	61.1
25	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1	60.1
26	59.1	59.1	59.1	59.1	59.1	59.1	59.1	59.1	59.1
27	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2	58.2
28	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2	57.2
29	56.2	56.2	56.2	56.2	56.2	56.2	56.2	56.2	56.2
30	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3	55.3
31	54.3	54.3	54.3	54.3	54.3	54.3	54.3	54.3	54.3
32	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4	53.4
33	52.4	52.4	52.4	52.4	52.4	52.4	52.4	52.4	52.4
34	51.4	51.4	51.4	51.4	51.4	51.4	51.4	51.4	51.4
35	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5
36	49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5	49.5
37	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6	48.6
38	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6	47.6
39	46.7	46.6	46.6	46.6	46.6	46.6	46.6	46.6	46.6
40	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7	45.7
41	44.7	44.7	44.7	44.7	44.7	44.7	44.7	44.7	44.7
42	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8	43.8
43	42.8	42.8	42.8	42.8	42.8	42.8	42.8	42.8	42.8
44	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.9	41.8
45	40.9	40.9	40.9	40.9	40.9	40.9	40.9	40.9	40.9
46	39.9	39.9	39.9	39.9	39.9	39.9	39.9	39.9	39.9
47	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0	39.0
48	38.0	38.0	38.0	38.0	38.0	38.0	38.0	38.0	38.0
49	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1	37.1
50	36.1	36.1	36.1	36.1	36.1	36.1	36.1	36.1	36.1
51	35.2	35.2	35.2	35.2	35.2	35.2	35.2	35.2	35.2
52	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3	34.3
53	33.3	33.3	33.3	33.3	33.3	33.3	33.3	33.3	33.3
54	32.4	32.4	32.4	32.4	32.4	32.4	32.4	32.4	32.4
55	31.5	31.5	31.5	31.5	31.5	31.5	31.5	31.5	31.5
56	30.6	30.6	30.6	30.6	30.6	30.6	30.6	30.6	30.6
57	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7	29.7
58	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8	28.8
59	27.9	27.9	27.9	27.9	27.9	27.9	27.9	27.9	27.9
60	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1	27.1
61	26.2	26.2	26.2	26.2	26.2	26.2	26.2	26.2	26.2
62	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.4	25.3
63	24.5	24.5	24.5	24.5	24.5	24.5	24.5	24.5	24.5
64	23.7	23.7	23.7	23.7	23.7	23.7	23.7	23.7	23.7
65	22.8	22.8	22.8	22.8	22.8	22.8	22.8	22.8	22.8
66	22.0	22.0	22.0	22.0	22.0	22.0	22.0	22.0	22.0
67	21.2	21.2	21.2	21.2	21.2	21.2	21.2	21.2	21.2
68	20.4	20.4	20.4	20.4	20.4	20.4	20.4	20.4	20.4

Ages	108	109	110	111	112	113	114	115	116
69	19.6	19.6	19.6	19.6	19.6	19.6	19.6	19.6	19.6
70	18.8	18.8	18.8	18.8	18.8	18.8	18.8	18.8	18.8
71	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0
72	17.2	17.2	17.2	17.2	17.2	17.2	17.2	17.2	17.2
73	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4
74	15.6	15.6	15.6	15.6	15.6	15.6	15.6	15.6	15.6
75	14.9	14.9	14.9	14.9	14.9	14.9	14.8	14.8	14.8
76	14.1	14.1	14.1	14.1	14.1	14.1	14.1	14.1	14.1
77	13.4	13.4	13.4	13.4	13.4	13.4	13.4	13.4	13.3
78	12.7	12.7	12.7	12.7	12.7	12.7	12.6	12.6	12.6
79	12.0	12.0	12.0	12.0	12.0	12.0	12.0	11.9	11.9
80	11.3	11.3	11.3	11.3	11.3	11.3	11.3	11.3	11.3
81	10.7	10.7	10.7	10.6	10.6	10.6	10.6	10.6	10.6
82	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
83	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4
84	8.9	8.9	8.9	8.8	8.8	8.8	8.8	8.8	8.8
85	8.3	8.3	8.3	8.3	8.3	8.3	8.3	8.3	8.2
86	7.8	7.8	7.8	7.8	7.8	7.8	7.8	7.7	7.7
87	7.3	7.3	7.3	7.3	7.3	7.3	7.3	7.3	7.2
88	6.9	6.9	6.9	6.9	6.9	6.8	6.8	6.8	6.8
89	6.5	6.5	6.5	6.4	6.4	6.4	6.4	6.4	6.3
90	6.1	6.1	6.1	6.1	6.0	6.0	6.0	6.0	5.9
91	5.7	5.7	5.7	5.7	5.7	5.7	5.6	5.6	5.6
92	5.4	5.4	5.4	5.4	5.3	5.3	5.3	5.3	5.2
93	5.1	5.1	5.1	5.0	5.0	5.0	5.0	5.0	4.9
94	4.8	4.8	4.8	4.8	4.7	4.7	4.7	4.7	4.6
95	4.5	4.5	4.5	4.5	4.5	4.5	4.4	4.4	4.3
96	4.3	4.3	4.3	4.3	4.2	4.2	4.2	4.2	4.1
97	4.1	4.1	4.1	4.0	4.0	4.0	4.0	3.9	3.9
98	3.9	3.9	3.9	3.9	3.8	3.8	3.8	3.7	3.7
99	3.7	3.7	3.7	3.7	3.7	3.6	3.6	3.6	3.5
100	3.6	3.5	3.5	3.5	3.5	3.5	3.4	3.4	3.3
101	3.4	3.4	3.4	3.4	3.4	3.3	3.3	3.3	3.2
102	3.3	3.3	3.3	3.3	3.2	3.2	3.2	3.1	3.1
103	3.2	3.2	3.2	3.2	3.1	3.1	3.1	3.0	3.0
104	3.1	3.1	3.1	3.1	3.1	3.0	3.0	3.0	2.9
105	3.1	3.1	3.0	3.0	3.0	3.0	3.0	2.9	2.8
106	3.0	3.0	3.0	3.0	3.0	3.0	2.9	2.9	2.8
107	3.0	3.0	3.0	3.0	3.0	2.9	2.9	2.9	2.8
108	3.0	3.0	3.0	3.0	2.9	2.9	2.9	2.8	2.8
109	3.0	3.0	3.0	2.9	2.9	2.9	2.9	2.8	2.8
110	3.0	3.0	3.0	2.9	2.9	2.9	2.9	2.8	2.7
111	3.0	2.9	2.9	2.9	2.9	2.9	2.8	2.8	2.7
112	2.9	2.9	2.9	2.9	2.9	2.9	2.8	2.8	2.7
113	2.9	2.9	2.9	2.9	2.9	2.8	2.8	2.7	2.7
114	2.9	2.9	2.9	2.8	2.8	2.8	2.8	2.7	2.6
115	2.8	2.8	2.8	2.8	2.8	2.7	2.7	2.7	2.6
116	2.8	2.8	2.7	2.7	2.7	2.7	2.6	2.6	2.5
117	2.7	2.6	2.6	2.6	2.6	2.6	2.5	2.5	2.4
118	2.5	2.5	2.5	2.4	2.4	2.4	2.4	2.3	2.2
119	2.3	2.3	2.2	2.2	2.2	2.2	2.1	2.1	2.0
120+	2.0	2.0	2.0	2.0	2.0	1.9	1.9	1.8	1.8

Ages	117	118	119	120+
0	84.5	84.5	84.5	84.5
1	83.7	83.7	83.7	83.7
2	82.7	82.7	82.7	82.7
3	81.7	81.7	81.7	81.7
4	80.8	80.8	80.8	80.8
5	79.8	79.8	79.8	79.8
6	78.8	78.8	78.8	78.8
7	77.8	77.8	77.8	77.8
8	76.8	76.8	76.8	76.8
9	75.8	75.8	75.8	75.8
10	74.8	74.8	74.8	74.8
11	73.8	73.8	73.8	73.8
12	72.8	72.8	72.8	72.8
13	71.9	71.9	71.9	71.9
14	70.9	70.9	70.9	70.9
15	69.9	69.9	69.9	69.9
16	68.9	68.9	68.9	68.9
17	67.9	67.9	67.9	67.9

Ages	117	118	119	120+
18	66.9	66.9	66.9	66.9
19	66.0	66.0	66.0	66.0
20	65.0	65.0	65.0	65.0
21	64.0	64.0	64.0	64.0
22	63.0	63.0	63.0	63.0
23	62.0	62.0	62.0	62.0
24	61.1	61.1	61.1	61.1
25	60.1	60.1	60.1	60.1
26	59.1	59.1	59.1	59.1
27	58.2	58.2	58.2	58.2
28	57.2	57.2	57.2	57.2
29	56.2	56.2	56.2	56.2
30	55.3	55.3	55.3	55.3
31	54.3	54.3	54.3	54.3
32	53.4	53.4	53.4	53.4
33	52.4	52.4	52.4	52.4
34	51.4	51.4	51.4	51.4
35	50.5	50.5	50.5	50.5
36	49.5	49.5	49.5	49.5
37	48.6	48.6	48.6	48.6
38	47.6	47.6	47.6	47.6
39	46.6	46.6	46.6	46.6
40	45.7	45.7	45.7	45.7
41	44.7	44.7	44.7	44.7
42	43.8	43.8	43.8	43.8
43	42.8	42.8	42.8	42.8
44	41.8	41.8	41.8	41.8
45	40.9	40.9	40.9	40.9
46	39.9	39.9	39.9	39.9
47	39.0	39.0	39.0	39.0
48	38.0	38.0	38.0	38.0
49	37.1	37.1	37.1	37.1
50	36.1	36.1	36.1	36.1
51	35.2	35.2	35.2	35.2
52	34.3	34.3	34.3	34.3
53	33.3	33.3	33.3	33.3
54	32.4	32.4	32.4	32.4
55	31.5	31.5	31.5	31.5
56	30.6	30.6	30.6	30.6
57	29.7	29.7	29.7	29.7
58	28.8	28.8	28.8	28.8
59	27.9	27.9	27.9	27.9
60	27.1	27.1	27.1	27.1
61	26.2	26.2	26.2	26.2
62	25.3	25.3	25.3	25.3
63	24.5	24.5	24.5	24.5
64	23.7	23.7	23.6	23.6
65	22.8	22.8	22.8	22.8
66	22.0	22.0	22.0	22.0
67	21.2	21.2	21.2	21.2
68	20.4	20.4	20.4	20.4
69	19.6	19.6	19.5	19.5
70	18.7	18.7	18.7	18.7
71	17.9	17.9	17.9	17.9
72	17.1	17.1	17.1	17.1
73	16.4	16.4	16.3	16.3
74	15.6	15.6	15.6	15.6
75	14.8	14.8	14.8	14.8
76	14.1	14.1	14.0	14.0
77	13.3	13.3	13.3	13.3
78	12.6	12.6	12.6	12.6
79	11.9	11.9	11.9	11.9
80	11.2	11.2	11.2	11.2
81	10.6	10.5	10.5	10.5
82	9.9	9.9	9.9	9.9
83	9.3	9.3	9.3	9.2
84	8.7	8.7	8.7	8.6
85	8.2	8.2	8.1	8.1
86	7.7	7.6	7.6	7.5
87	7.2	7.1	7.1	7.0
88	6.7	6.7	6.6	6.6
89	6.3	6.2	6.2	6.1
90	5.9	5.8	5.7	5.7
91	5.5	5.4	5.4	5.3

Ages	117	118	119	120+
92	5.2	5.1	5.0	4.9
93	4.8	4.8	4.7	4.6
94	4.5	4.4	4.3	4.2
95	4.3	4.2	4.0	3.9
96	4.0	3.9	3.8	3.7
97	3.8	3.7	3.5	3.4
98	3.6	3.5	3.3	3.2
99	3.4	3.3	3.1	3.0
100	3.2	3.1	2.9	2.8
101	3.1	3.0	2.8	2.6
102	3.0	2.8	2.6	2.5
103	2.9	2.7	2.5	2.3
104	2.8	2.6	2.4	2.2
105	2.7	2.6	2.3	2.1
106	2.7	2.5	2.3	2.1
107	2.7	2.5	2.3	2.1
108	2.7	2.5	2.3	2.0
109	2.6	2.5	2.3	2.0
110	2.6	2.5	2.2	2.0
111	2.6	2.4	2.2	2.0
112	2.6	2.4	2.2	2.0
113	2.6	2.4	2.2	1.9
114	2.5	2.4	2.1	1.9
115	2.5	2.3	2.1	1.8
116	2.4	2.2	2.0	1.8
117	2.3	2.1	1.9	1.6
118	2.1	1.9	1.7	1.4
119	1.9	1.7	1.3	1.1
120+	1.6	1.4	1.1	1.0

(e) *Mortality rates.* The following are the mortality rates used to calculate the tables set forth in paragraphs (b), (c) and (d) of this section.

TABLE 4 TO PARAGRAPH (e)

Age	Probability of death
0	0.001765
1	0.000442
2	0.000293
3	0.000232
4	0.000177
5	0.000162
6	0.000153
7	0.000145
8	0.000132
9	0.000127
10	0.000128
11	0.000135
12	0.000146
13	0.000165
14	0.000192
15	0.000224
16	0.000253
17	0.000277
18	0.000293
19	0.000305
20	0.000314
21	0.000344
22	0.000378
23	0.000421
24	0.000467
25	0.000520
26	0.000581
27	0.000630
28	0.000677
29	0.000720
30	0.000762
31	0.000797
32	0.000822
33	0.000830
34	0.000826
35	0.000818
36	0.000813
37	0.000818
38	0.000830
39	0.000847
40	0.000872
41	0.000902
42	0.000938
43	0.000974
44	0.001012
45	0.001061
46	0.001128
47	0.001223
48	0.001345
49	0.001488
50	0.001661
51	0.001883
52	0.002134
53	0.002413
54	0.002722
55	0.003057
56	0.003418
57	0.003805
58	0.004213
59	0.004646
60	0.005104
61	0.005587
62	0.006102
63	0.006655
64	0.007255
65	0.007913
66	0.008265
67	0.008687
68	0.009194
69	0.009804
70	0.010535
71	0.011413
72	0.012454
73	0.013684
74	0.015121
75	0.016798
76	0.018740
77	0.020993
78	0.023598
79	0.026624
80	0.030122
81	0.034190
82	0.038892
83	0.044271
84	0.050391
85	0.057285
86	0.064967
87	0.073466
88	0.082774
89	0.092864
90	0.103667
91	0.115152
92	0.127474
93	0.140876
94	0.155859
95	0.173011
96	0.188348
97	0.205840
98	0.224127
99	0.243120
100	0.262731
101	0.282787
102	0.303096
103	0.323605

TABLE 4 TO PARAGRAPH (e)—Continued

TABLE 4 TO PARAGRAPH (e)—Continued

TABLE 4 TO PARAGRAPH (e)—Continued

Age	Probability of death
104	0.344149
105	0.362406
106	0.373952
107	0.382053
108	0.384203
109	0.386443
110	0.388694
111	0.390860
112	0.393195
113	0.395445
114	0.397687
115	0.400000
116	0.400000
117	0.400000
118	0.400000
119	0.400000
120	1.000000

(f) *Applicability dates*—(1) *In General.* The life expectancy tables and Uniform Lifetime Table set forth in this section apply for distribution calendar years beginning on or after January 1, 2021. For life expectancy tables and the Uniform Lifetime Table applicable for earlier distribution calendar years, see § 1.401(a)(9)–9, as set forth in 26 CFR part 1 revised April 1, 2019 (formerly applicable § 1.401(a)(9)–9).

(2) *Application to life expectancies that may not be recalculated*—(i) *Applicability of current tables.* If an employee died before January 1, 2021, and, under the rules of § 1.401(a)(9)–5, the distribution period that applies for a calendar year following the calendar year of the employee's death is equal to a single life expectancy calculated as of the calendar year of the employee's death (or, if applicable, the following calendar year), reduced by 1 for each subsequent year, then that life expectancy is reset as provided in paragraph (f)(2)(ii) of this section. Similarly, if an employee's sole beneficiary is the employee's surviving spouse, and the spouse dies before January 1, 2021, then the spouse's life expectancy for the calendar year of the spouse's death (which is used to determine the applicable distribution period for later years) is reset as provided in paragraph (f)(2)(ii) of this section.

(ii) *Determination of applicable distribution period.* With respect to a life expectancy described in paragraph (f)(2)(i) of this section, the distribution period that applies for a distribution calendar year beginning on or after January 1, 2021, is determined by using the Single Life Table in paragraph (b) of this section to determine initial life expectancy for the age of the relevant individual in the relevant calendar year and then reducing the resulting distribution period by 1 for each subsequent year. For example, assume that an employee died at age 80 in 2018 and the employee's designated beneficiary (who was not the employee's spouse) was age 75 in the year of the employee's death. For 2019, the distribution period that would have applied for the beneficiary was 12.7 years (the period applicable for a 76 year old under the Single Life Table in formerly applicable § 1.401(a)(9)–9), and for 2020, it would have been 11.7 years (the original distribution period, reduced by 1 year). For 2021, the applicable distribution period would be 12.0 years (the 14.0 year life expectancy for a 76 year old under the Single Life Table in paragraph (b) of this section, reduced by 2 years).

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

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Part V

Small Business Administration

13 CFR Parts 121, 124, 125, et al.
Consolidation of Mentor Protégé Programs and Other Government Contracting Amendments; Proposed Rule

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 121, 124, 125, 126, 127, and 134

RIN 3245–AG94

Consolidation of Mentor Protégé Programs and Other Government Contracting Amendments

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: In response to President Trump's government-wide regulatory reform initiative, the Small Business Administration (SBA) initiated a review of its regulations to determine which might be revised or eliminated. As a result, SBA is proposing to merge the 8(a) Business Development (BD) Mentor-Protégé Program and the All Small Mentor-Protégé Program to eliminate confusion and remove unnecessary duplication of functions within SBA. This rule proposes to eliminate the requirement that 8(a) Participants seeking to be awarded an 8(a) contract as a joint venture submit the joint venture to SBA for review and approval prior to contract award, revise several 8(a) BD program regulations to reduce unnecessary or excessive burdens on 8(a) Participants, and clarify other related regulatory provisions to eliminate confusion among small businesses and procuring activities. In addition, except for orders and Blanket Purchase Agreements issued under the General Services Administration's Federal Supply Schedule Program, the rule proposes to require a business concern to recertify its size and/or socioeconomic status for all set-aside orders under unrestricted multiple award contracts (MACs) The rule also proposes to require a business concern to recertify its socioeconomic status for all set-aside orders where the required socioeconomic status for the order differs from that of the underlying set-aside MAC contract (*e.g.,* HUBZone set-aside order against a small business set-aside MAC). Finally, except for orders or Blanket Purchase Agreements issued under any Federal Supply Schedule contract, the rule also allows for size and/or socioeconomic protests at the order-level for set-aside orders issued against unrestricted MACs, or for set-aside orders based on a different socioeconomic status from the underlying set-aside MAC.

DATES: Comments must be received on or before January 17, 2020.

ADDRESSES: You may submit comments, identified by RIN 3245–AG94 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail, for Paper, Disk, or CD/ROM Submissions:* Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416.
- *Hand Delivery/Courier:* Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416.

SBA will post all comments on *http://www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *http://www.regulations.gov,* please submit the information to Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416, or send an email to *brenda.fernandez@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 the information and make the final determination of whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, Washington, DC 20416; (202) 205–7337; *brenda.fernandez@sba.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

On January 30, 2017, President Trump issued Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs'', which is designed to reduce unnecessary and burdensome regulations and to control costs associated with regulations. In response to the President's directive to simplify regulations, SBA initiated a review of its regulations to determine which might be revised or eliminated. Based on this analysis, SBA has identified provisions in many areas of its regulations that can be simplified or eliminated. Firstly, this proposed rule would merge the 8(a) BD Mentor-Protégé Program and the All Small Mentor-Protégé Program. This rule also proposes to eliminate the requirement that 8(a) Participants seeking to be awarded an 8(a) contract as a joint venture must submit the joint venture to SBA for review and approval prior to contract award. This rule also proposes to make several changes to the 8(a) BD Program to eliminate or reduce unnecessary or excessive burdens on 8(a) Participants. As part of this proposed rulemaking process, SBA also held tribal consultations pursuant to Executive Order 13175, Tribal Consultations, in Anchorage, AK, Albuquerque, NM and Oklahoma City, OK to provide interested tribal representatives with an opportunity to discuss their views on various 8(a) BD-related issues. SBA considers tribal consultation meetings a valuable component of its deliberations and believes that these tribal consultation meetings allowed for constructive dialogue with the Tribal community, Tribal Leaders, Tribal Elders, elected members of Alaska Native Villages or their appointed representatives, and principals of tribally-owned and Alaska Native Corporation (ANC) owned firms participating in the 8(a) BD Program. SBA has taken these discussions into account in drafting this proposed rule.

SBA seeks to combine the 8(a) BD Mentor-Protégé Program and the All Small Mentor-Protégé Program at this time in order to eliminate confusion regarding perceived differences between the two Programs, remove unnecessary duplication of functions within SBA, and establish one, unified staff to better coordinate and process mentor-protégé applications. SBA originally established a mentor-protégé program for 8(a) Participants a little more than twenty years ago. 63 FR 35726, 35764 (June 30, 1998). The purpose of that program was to encourage approved mentors to provide various forms of business assistance to eligible 8(a) Participants to aid in their development. On September 27, 2010, the Small Business Jobs Act of 2010 (Jobs Act), Public Law 111–240 was enacted. The Jobs Act was designed to protect the interests of small businesses and increase opportunities in the Federal marketplace. The Jobs Act was drafted by Congress in recognition of the fact that mentor-protégé programs serve an important business development function for small businesses and therefore included language authorizing SBA to establish separate mentor-protégé programs for the Service-Disabled Veteran-Owned Small Business Concern (SDVO SBC) Program, the HUBZone Program, and the Women-Owned Small Business (WOSB) Program, each of which was modeled on SBA's existing mentor-protégé program available to 8(a) Participants. *See* section 1347(b)(3) of the Jobs Act. Thereafter, on January 2, 2013, the National Defense Authorization Act for Fiscal Year 2013 (NDAA 2013), Public Law 112–239 was enacted. Section 1641 of the NDAA 2013 authorized SBA to establish a mentor-protégé program for all small

business concerns. This section further provided that a small business mentor-protégé program must be identical to the 8(a) BD Mentor-Protégé Program, except that SBA could modify each program to the extent necessary, given the types of small business concerns to be included as protégés.

Subsequently, SBA published a Final Rule in the **Federal Register** combining the authorities contained in the Jobs Act and the NDAA 2013 to create a mentor-protégé program for all small businesses. 81 FR 48558 (July 25, 2016).

Currently, the mentor-protégé program available to firms participating in the 8(a) BD Program (contained in 13 CFR 124.520) is used as a business development tool in which mentors provide diverse types of business assistance to eligible 8(a) BD protégés. This assistance may include, among other things, technical and/or management assistance; financial assistance in the form of equity investments and/or loans; subcontracts; and/or assistance in performing Federal prime contracts through joint venture arrangements. The explicit purpose of the 8(a) BD Mentor-Protégé relationship is to enhance the capabilities of protégés and to improve their ability to successfully compete for both government and commercial contracts. Similarly, the All Small Mentor-Protégé Program is designed to require approved mentors to aid protégé firms so that they may enhance their capabilities, meet their business goals, and improve their ability to compete for contracts. The purposes of the two programs are identical. In addition, the benefits available under both programs are identical. Small businesses and 8(a) Program Participants receive valuable business development assistance and any joint venture formed between a protégé firm and its SBA-approved mentor receives an exclusion from affiliation, such that the joint venture will qualify as a small business provided the protégé individually qualifies as small under the size standard corresponding to the NAICS code assigned to the procurement. A protégé firm may enter a joint venture with its SBA-approved mentor and be eligible for any contract opportunity for which the protégé qualifies. If a protégé firm is an 8(a) Program Participant, a joint venture between the protégé and its mentor could seek any 8(a) contract, regardless of whether the mentor-protégé agreement was approved through the 8(a) BD Mentor-Protégé Program or the All Small Mentor-Protégé Program. Moreover, a firm could be certified as an 8(a) Participant after its mentor-protégé relationship has been approved by SBA through the All Small Mentor-Protégé Program and be eligible for 8(a) contracts as a joint venture with its mentor once certified.

Because the benefits and purposes of the two programs are identical, SBA believes that having two separate mentor-protégé programs is unnecessary and causes needless confusion in the small business community. As such, this proposed rule would eliminate a separate 8(a) BD Mentor-Protégé Program and continue to allow any 8(a) Participant to enter a mentor-protégé relationship through the All Small Mentor-Protégé Program. Specifically, the proposed rule would revise § 124.520 to merely recognize that an 8(a) Participant, as any other small business, may participate in SBA's Small Business Mentor-Protégé Program. In merging the 8(a) BD Mentor-Protégé Program with the All Small Mentor-Protégé Program, the proposed rule would also make conforming amendments to SBA's size regulations (13 CFR part 121), the joint venture provisions (13 CFR 125.8), and the All Small Mentor-Protégé Program regulations (13 CFR 125.9).

As stated previously, SBA has also taken this action partly in response to the President's directive that each agency review its regulations. Therefore, this rule also proposes to revise regulations pertaining to the 8(a) BD and size programs in order to further reduce unnecessary or excessive burdens on small businesses and to eliminate confusion or more clearly delineate SBA's intent in certain regulations. Specifically, this rule proposes additional changes to the size and socioeconomic status recertification requirements for orders issued against MACs. A detailed discussion of these proposed changes is contained below in the Section-by-Section Analysis.

II. Section-by-Section Analysis

Section 121.103(b)(6)

The proposed rule would amend the references to SBA's mentor-protégé programs in this provision, which specifying that a protégé firm cannot be considered affiliated with its mentor based solely on assistance received by the protégé under the mentor-protégé agreement. The proposed rule would eliminate the cross-reference to the regulation regarding the 8(a) BD Mentor-Protégé Program (13 CFR 124.520), leaving only the reference to the regulation regarding the All Small Business Mentor-Protégé Program.

Section 121.103(g)

The proposed rule would amend the newly organized concern rule contained in § 121.103(g) by clarifying that affiliation may be found where both former and ''current'' officers, directors, principal stockholders, managing members, or key employees of one concern organize a new concern in the same or related industry or field of operation, and serve as the new concern's officers, directors, principal stockholders, managing members, or key employees. The rule would merely add the word ''current'' to the regulatory text to ensure that affiliation may arise where the key individuals are still associated with the first company. SBA believes that such a finding of affiliation is authorized in the present regulations, but merely seeks to clarify its intent to make sure there is no confusion.

Section 121.103(h)

The proposed rule would amend the introductory text to § 121.103(h) to revise the requirements for joint ventures. SBA believes that a joint venture is not an on-going business entity, but rather something that is formed for a limited purpose and duration. If two or more separate business entities seek to join together through another entity on a continuing, unlimited basis, SBA views that as a separate business concern with each partner affiliated with each other. To capture SBA's intent on limited scope and duration, SBA's current regulations provide that a joint venture is something that can be formed for no more than three contracts over a two-year period. If the parties intend to jointly seek work beyond three contracts or beyond two years from the date of the first award, they must form a new joint venture entity. That new entity would then be able to perform an additional three contracts over two years from the date of its first award. Several firms have commented to SBA that the three-contract limit unduly restricts small business and can disrupt normal business operations. SBA does not seek to impose unnecessary burdens on small businesses but continues to believe that a joint venture should be a limited duration vehicle. In response to these concerns, SBA proposes to eliminate the three-contract limit for a joint venture, but continue to prescribe that a joint venture cannot exceed two years from the date of its first award. In addition, the proposed rule would clarify SBA's current intent that a novation to the joint venture would start the two-year period if that were the first award received by the joint venture. The

change removing the limit of three awards to any joint venture would relieve small businesses of the requirement of forming additional joint venture entities to perform a fourth contract within that two-year period. The proposed rule attempts to lessen the burden on small businesses, while still preserving SBA's belief that a joint venture is not intended to be an on-going business entity.

In addition, SBA is interested in comments regarding the exception to affiliation for joint ventures composed of multiple small businesses in which firms enter and leave the joint venture based on their size status. In this scenario, in an effort to retain small business status, joint venture partners expel firms that have exceeded the size standard and then possibly add firms that qualify under the size standard. Generally, this should not be a problem because joint ventures are limited in duration to two years and generally can be awarded no more than three contracts during those two years. However, if the joint venture is awarded a Federal Supply Schedule (FSS) contract or any other multiple award contract vehicle, the awarding of the multiple award contract itself counts against the limit of three contract awards that a joint venture can receive, but individual orders do not count against the limit. As such, a joint venture that is awarded a multiple award contract could receive many orders beyond the two-year limitation for joint venture awards (since the contract was awarded within that two-year period), and could remain small for any order requiring recertification simply by exchanging one joint venture partner for another (*i.e.,* a new small business for one that has grown to be other than small). SBA never intended for the composition of joint ventures to be fluid. The joint venture generally should have the same partners throughout its lifetime, unless one of the partners is acquired. SBA considers a joint venture composed of different partners to be a different joint venture than the original one. To reflect this understanding, SBA could specify that the size of a joint venture outside of the mentor-protégé program will be determined based on the current size status and affiliations of all past and present joint venture partners, even if a partner has left the joint venture. SBA invites comment on this proposal and whether there are alternative ways to address this issue.

The rule also proposes to add clarifying language to the introductory text of § 121.103(h) to recognize that, although a joint venture cannot be populated with individuals intended to perform contracts awarded to the joint venture, the joint venture can directly employ administrative personnel and such personnel may specifically include Facility Security Officers.

It has also been brought to SBA's attention that some procuring agencies will not award a contract requiring a facility security clearance to a joint venture if the joint venture itself does not have such clearance, even if both partners to the joint venture individually have such clearance. SBA does not believe that such a restriction is appropriate and seeks comments on how best to address that in a final rule. SBA is considering a provision which would require either the joint venture itself or the lead small business partner to the joint venture to have the required facility security clearance. If such a provision were finalized, a joint venture lacking its own separate facility security clearance could still be awarded a contract requiring such a clearance provided the lead small business partner to the joint venture had the required facility security clearance and committed to keep at its cleared facility all records relating to the contract awarded to the joint venture. Additionally, if it is established that the security portion of the contract requiring a facility security clearance is ancillary to the principal purpose of the procurement, SBA believes that the non-lead partner to the joint venture (which may include a large business mentor) could possess such clearance. SBA specifically requests comments on this possible provision as well as other recommendations regarding how best to address this perceived problem.

The rule would also remove current § 121.103(h)(3)(iii), which provides that a joint venture between a protégé firm and its mentor that was approved through the 8(a) BD Mentor-Protégé Program is considered small provided the protégé qualifies as individually small. Because this proposed rule would eliminate the 8(a) BD Mentor-Protégé Program as a separate program, this provision is no longer needed.

The proposed rule also clarifies how to account for joint venture receipts and employees during the process of determining size for a joint venture partner. The joint venture partner must include its percentage share of joint venture receipts and employees in its own receipts or employees. The appropriate percentage share is the same percentage figure as the percentage figure corresponding to the joint venture partner's share of work performed by the joint venture.

Section 121.402

This rule proposes to amend how NAICS codes are applied to task orders to ensure that the NAICS codes assigned to specific procurement actions, and the corresponding size standards, are an accurate reflection of the contracts and orders being awarded and performed. Under the proposed rule, a contracting officer would be required to assign a single NAICS code for each order issued against a Multiple Award Contract (MAC), and that NAICS code must be a NAICS code that is included in the underlying MAC and represents the principal purpose of the order. SBA believes that the NAICS code assigned to a task order must reflect the principal purpose of that order. Currently, based on the business rules of the Federal Procurement Data System (FPDS), if a MAC is assigned a service NAICS code, then that service NAICS code flows down to each individual order under that MAC. SBA does not believe it is appropriate for a task order that is nearly entirely for supplies to have a service NAICS code. In such a case, a firm being awarded such an order would not have to comply with the nonmanufacturer rule. In particular, set-aside orders should be assigned a manufacturing/supply NAICS code, so that the nonmanufacturer rule will apply to the order if it is awarded to a nonmanufacturer. Additionally, the current method for NAICS code assignment can also be problematic where a MAC is assigned a NAICS code for supplies but a particular order under that MAC is almost entirely for services. In such a case, firms that qualified as small for the larger employee-based size standard associated with a manufacturing/supply NAICS code may not qualify as small businesses under a smaller receipts-based services size standard. As such, because the order is assigned the manufacturing/supply NAICS code associated with the MAC, firms that should not qualify as small for a particular procurement that is predominantly for services may do so. Thus, this proposed rule attempts to ensure that the NAICS codes assigned to specific procurement actions, and the corresponding size standards, are an accurate reflection of the contracts and orders being awarded and performed.

There will still be anomalies where a procuring agency seeks to award an order whose principal purpose is different than the assigned NAICS code for the MAC until the Federal Acquisition Regulation (FAR) and the FPDS is amended to include multiple NAICS codes at the contract level. SBA does not believe that the order should

be assigned a NAICS code that does not properly reflect its principal purpose. SBA believes that the better approach would be to fulfill such requirement through a different contracting vehicle.

Sections 121.404(a)(1), 124.503(i), 125.18(d), and 127.504(c)

Size Status

SBA has been criticized for allowing agencies to receive credit towards their small business goals for awards made to firms that no longer qualify as small. SBA believes that much of this criticism is misplaced. Where a small business concern is awarded a small business set-aside contract with a duration of not more than five years and grows to be other than small during the performance of the contract, some have criticized the exercise of an option as an award to an other than small business. SBA disagrees with such a characterization. Small business set-aside contracts are restricted only to firms that qualify as small as of the date of a firm's offer for the contract. A firm's status as a small business is relevant to its qualifying for the award of the contract. If a concern qualifies as small for a contract with a duration of not more than five years, it is considered a small business throughout the life of that contract. Even for MACs that are set-aside for small business, once a concern is awarded a contract as a small business it is eligible to receive orders under that contract and perform as a small business. Again, in such a case, size was relevant to the initial award of the contract. Any competitor small business concern could protest the size status of an apparent successful offeror for a small business set-aside contract (whether single award or multiple award), and render a concern ineligible for award where SBA finds that the concern does not qualify as small under the size standard corresponding to the NAICS code assigned to the contract. Furthermore, firms awarded a long-term contract must recertify their size status at five years and every option thereafter. Firms are eligible to receive orders under that contract and perform as a small business so long as they continue to recertify as small at the required times (*e.g.,* at five years and every option thereafter). Not allowing a concern that legitimately qualified at award and/or recertified later as small to receive orders and continue performance as a small business during the base and option periods, even if it has naturally grown to be other than small, would discourage firms from wanting to do business with the Government, would be disruptive to the procurement process, and would disincentivize contracting officers from using small business set-asides.

SBA agrees that contract performance by a concern that merges with, acquires, or is acquired by another business concern and no longer qualifies as small should not count towards small business goals. However, SBA already requires a concern to recertify its size status within 30 days of a merger, sale, or acquisition becoming final. *See* 13 CFR 121.404(g). Under the current regulation, if the contractor is other than small, the agency can no longer count the options or orders issued pursuant to the contract, from that point forward, towards its small business goals. *Id.*

SBA, believes, however, that there is a legitimate concern where a concern self-certifies as small for an unrestricted MAC and at some point later in time when the concern no longer qualifies as small the contracting officer seeks to award an order as a small business set-aside and the firm uses its self-certification as a small business for the underlying unrestricted MAC. Under the current process, size status for an unrestricted MAC is generally determined as of the date a firm submits its offer for the MAC. If a concern self-certifies as small at the time of its offer for the underlying MAC, the concern is generally considered to be small for goaling purposes for each order issued against the contract, unless a contracting officer requests a new size certification in connection with a specific order. Therefore, when a contracting officer seeks to set-aside an order for small business off an unrestricted MAC, the firm's size relates back to its self-certification for the underlying MAC. As such, orders may be set-aside for small businesses and a concern may be awarded one or more orders as a small business even though it does not currently qualify as small and may not have qualified as small for several years.

SBA agrees that this situation needs to be addressed. A firm's status as a small business does not generally affect whether the firm does or does not qualify for the award of an unrestricted MAC contract. As such, competitors are very unlikely to protest the size of a concern that self-certifies as small for an unrestricted MAC. In SBA's view, where a contracting officer sets aside an order for small business under an unrestricted MAC, the order is the first time size status is important. That is the first time that some firms will be eligible to compete for the order while others will be excluded from competition because of their size status. As noted above, no one is considering protesting the size or status of a firm at the time an unrestricted MAC is awarded. It is only when an order is restricted by size status that firms focus on their competitors' size status. To allow a firm's self-certification for the underlying MAC to control whether a firm is small at the time of an order years after the MAC was awarded does not make sense to SBA.

SBA has considered several alternative proposals. If an order under an unrestricted MAC is set-aside exclusively for small business (*i.e.,* small business set-aside, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), SBA considered requiring a concern to certify its size status and qualify as such at the time it submits its initial offer, which includes price, for the particular order under all unrestricted MACs. SBA has also considered exempting FSS contracts from any recertification requirement, and instead applying it only to all other MACs. SBA does not seek to disrupt the procurement process, but rather to ensure that small business set-aside awards are made to firms that qualify as small at the time of the award. GSA is concerned that requiring firms to certify their size status for an order that is set-aside under a FSS would discourage firms from wanting to do business with the Government, would dissuade contracting officers from setting aside orders, and that this will in turn hurt small businesses.

In considering the issue, SBA looked at the data for orders that were awarded as small business set-asides off unrestricted base multiple award vehicles in FY 2018. In total, 8,666 orders were awarded as small business set-asides off unrestricted MACs in FY 2018. Of those set-aside orders, 10% are estimated to have been awarded to firms that no longer qualified as small under the NAICS code size standard at the time of the order award. Although the vast majority of set-aside orders under unrestricted MACs were awarded off of FSS contracts. Further, it is estimated that only 7.1% of small business set-aside orders off the FSS were awarded to firms that no longer qualified as small under the NAICS code size standard at the time of the order (510 out of 7,266 orders). That amounted to 12.1% of the dollars set-aside for small business off the FSS ($129.6 million to firms that no longer qualified as small out of a total of $1.0723 billion in small business set-aside orders). Whereas, it is estimated that 49.4% of small business set-aside orders off of government-wide acquisition contracts (GWACs) were awarded to firms that no longer

qualified as small under the NAICS code size standard at the time of the order (261 out of 528 orders). That amounted to 67% of the dollars set-aside for small business off of GWACs ($119.6 million to firms that no longer qualified as small out of a total of $178.6 million in small business set-aside orders). SBA then considered the number and dollar value of new orders that were awarded as small business set-asides off unrestricted base multiple award vehicles in FY 2018 using the size standard ''exceptions'' that apply in some of SBA's size standards (*e.g.,* the IT Value-Added Reseller exception to NAICS 541519). Taking into account all current size standards exceptions, which allow a firm to qualify under an alternative size standard for certain types of contracts, it is estimated that 6.5% of small business set-aside orders off the FSS were awarded to firms that no longer qualified as small at the time of the order (468 out of 7,266 orders). That amounted to 11.3% of the dollars set-aside for small business off the FSS ($120.7 million to firms that no longer qualified as small out of a total of $1.0723 billion in small business set-aside orders). Considering exceptions for set-aside orders off of GWACs, it is estimated that 11.6% were awarded to firms that no longer qualified as small at the time of the order (61 out of 528 orders). That amounted to 39.5% of the dollars set-aside for small business off of GWACs ($70.5 million to firms that no longer qualified as small out of a total of $178.6 million in small business set-aside orders). It is not possible to tell from FPDS whether the ''exception'' size standard applied to the contract or whether the agency applied the general size standard for the identified NAICS code. Thus, all that can be said with certainty is that for small business set-aside orders off of the FSS, between 11.3% and 12.1% of the order dollars set-aside for small business were awarded to firms that no longer qualified as small. This amounted to somewhere between $120.7 million and $129.6 that were awarded to firms that no longer qualified as small. For GWACs, the percentage of orders and order dollars being awarded to firms that no longer qualify as small is significantly greater. Between 39.5% and 67.0% of the order dollars set-aside for small business off GWACs were awarded to firms that no longer qualified as small. This amounted to somewhere between $70.5 million and $119.6 million that were awarded to firms that no longer qualified as small. So, set-aside orders off of GWACs, for example, that may potentially go to other than small businesses are more significant at 11.6–49.4%. However, the data shows that discretionary set-asides under the FSS programs have proven effective in making awards to small business under the schedules program. The data also shows that the percent of dollars going to other than small business off of FSS set-asides is limited. Thus, SBA is considering exempting FSS contracts from the recertification requirement as it may not be efficient. SBA determined that the added burden to the public and Government to implement additional control measures and the potential effect on small business participation in Government contracting outweighed any potential benefits from trying to mitigate the limited risk. As such, this rule proposes to exempt the FSS contracts from the rule.

SBA believes that a contracting vehicle that intends to award to small businesses but instead permits as much as 49.4% of its orders and between 39.5% and 67% of its dollars to be awarded to firms that do not qualify as small is the appropriate area to address. As such, pursuant to this proposed rule, except for orders or Blanket Purchase Agreements issued under any FSS contract, if an order under an unrestricted MAC is set-aside exclusively for small business (*i.e.,* small business set-aside, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), a concern must recertify its size status and qualify as such at the time it submits its initial offer, which includes price, for the particular order. A firm whose size certification in SAM is current and accurate will not need to submit a new certification or additional documentation.

For a MAC that is set aside for small business (*i.e.,* small business set-aside, 8(a) small business, SDVO small business, HUBZone small business, or WOSB), the proposed rule would generally set size statusas of the date of the offer for the underlying MAC itself. A concern that is small at the time of its offer for the MAC would be considered small for each order issued against the contract, unless a contracting officer requests a size recertification in connection with a specific order. As is currently the case, a contracting officer has the discretion to request recertification of size status on MAC orders. If that occurs, size status would be determined at the time of the order. That would not be a change from the current regulations.

Socioeconomic Status

Where the required status for an order differs from that of the underlying contract (*e.g.,* the MAC is a small business set-aside award, and the procuring agency seeks to restrict competition on the order to only certified HUBZone small business concerns), SBA believes that a firm must qualify for the socioeconomic status of a set-aside order at the time it submits an offer for that order. Although size may flow down from the underlying contract, status in this case cannot. Similar to where a procuring agency seeks to compete an order on an unrestricted procurement as a small business set-aside and SBA would require offerors to qualify as small with respect to that order (except for orders under FSS contracts), SBA believes that where the socioeconomic status is first required at the order level, an offeror seeking that order must qualify for the socioeconomic status of the set-aside order when it submits its offer for the order.

Under current policy and regulations, where a contracting officer seeks to restrict competition of an order off an unrestricted MAC to eligible 8(a) Participants only, the contracting officer must offer the order to SBA to be awarded through the 8(a) program, and SBA must accept the order for the 8(a) program. In determining whether a concern is eligible for such an 8(a) order, SBA would apply the provisions of the Small Business Act and its current regulations which require a firm to be an eligible Program Participant as of the date set forth in the solicitation for the initial receipt of offers for the order. SBA requests comments on the alternative approaches considered as well as any other approaches that would reduce the set-aside awards to firms that do not qualify as small or qualify for the socioeconomic status of a set-aside order while at the same time not disrupting the procurement process or imposing unnecessary burdens on small businesses or contracting officers.

The rule proposes to make these changes in § 121.404(a)(1) for size, § 124.503(i) for 8(a) BD eligibility, § 125.18(d) for SDVO eligibility, and § 127.504(c) for WOSB eligibility.

Section 121.404

In addition to the revision to § 121.404(a)(1) identified above, the rule proposes to make several other changes or clarifications to § 121.404. In order to make this section easier to use and understand, the proposed rule would add headings to each subsection, which

would identify the subject matter of the subsection.

The rule proposes to amend § 121.404(b), which requires a firm applying to SBA's programs to qualify as a small business for its primary industry classification as of the date of its application. The rule would eliminate references to SBA's small disadvantaged business (SDB) program as obsolete, and add a reference to the WOSB program.

The proposed rule would also amend § 121.404(d) to clarify that size status for purposes of compliance with the nonmanufacturer rule, the ostensible subcontractor rule and joint venture agreement requirements is determined as of the date of the final proposal revision for negotiated acquisitions and final bid for sealed bidding. Currently, only compliance with the nonmanufacturer rule is specifically addressed in this paragraph, but SBA's policy has been to apply the same rule to determine size with respect to the ostensible subcontractor rule and joint venture agreement requirements. This would not be a change in policy, but rather a clarification of existing policy.

The proposed rule would also add a clarifying sentence to § 121.404(e) that would recognize that prime contractors may rely on the self-certifications of their subcontractors provided they do not have a reason to doubt any specific self-certification. SBA believes that this has always been the case, but has added this clarifying sentence, nevertheless, at the request of many prime contractors.

The proposed rule would make several revisions to the size recertification provisions in § 121.404(g). First, the recertification rule pertaining to a joint venture that had previously received a contract as a small business was not clear. If a partner to the joint venture has been acquired, is acquiring or has merged with another business entity, the joint venture must recertify its size status. In order to remain small, however, it was not clear whether only the partner which has been acquired, is acquiring or has merged with another business entity needed to recertify its size status or whether all partners to the joint venture had to do so. SBA believes that the intent of the regulation was to require size recertification only for the affected partner. To do otherwise could unfairly prejudice the joint venture and the procuring activity. For example, assume that a joint venture has two partners, a 75% managing partner and a 25% non-managing partner. In order to have initially been awarded a contract as a small business, both partners to the joint venture had to individually qualify as small (unless one was an SBA-approved mentor of the other). If since the date of the award the 75% partner has naturally grown to exceed the size standard assigned to the contract and the 25% partner has been acquired by another small business, the joint venture could not recertify as small if both partners had to recertify their individual size status even if the 25% partner still qualified as small after its acquisition. SBA does not believe that would be fair to the 75% partner or to the procuring activity, which could no longer count the contract as an award to small business. Just as SBA allows, under certain conditions, a contract to continue to count as an award to small business if a concern awarded the contract has grown to exceed the applicable size standard after award, so too should a contract to a joint venture continue to count as an award to small business if the non-affected partner has grown to be other than small and the partner that has been acquired continues to be small after the acquisition. Thus, the proposed rule clarifies that only the partner to the joint venture that has been acquired, is acquiring, or has merged with another business entity must recertify its size status in order for the joint venture to recertify its size.

Additionally, the proposed rule clarifies that if a merger or acquisition causes a firm to recertify as an other than small business concern between time of offer and award, then the recertified firm is not considered a small business for the solicitation. Under this proposed rule, SBA would accept size protests with specific facts showing that an apparent awardee of a set-aside has recertified or should have recertified as other than small due to a merger or acquisition before award.

The proposed rule would also clarify that recertification is not required when the ownership of a concern that is at least 51% owned by an entity (*i.e.,* tribe, ANC, or Community Development Corporation (CDC)) changes to or from a wholly-owned business concern of the same entity, as long as the ultimate owner remains that entity. When the small business continues to be owned to the same extent by the tribe, ANC or CDC, SBA does not believe that the real ownership of the concern has changed, and, therefore that recertification is not needed. The proposed rule would make this same change to § 121.603 for 8(a) contracts as well.

Finally, the proposed rule would amend § 121.404(g)(3) to specifically permit a contracting officer to request size recertification as he or she deems appropriate at any point in a long-term contract. SBA believes that this authority exists within the current regulatory language but is merely articulating it more clearly in this rule.

Section 121.406

The proposed rule would merely correct a typographical error by replacing the word ''provided'' with the word ''provide.''

Section 121.702

The proposed rule would clarify the size requirements applicable to joint ventures in the Small Business Innovation Research (SBIR) program. Although the current regulation authorizes joint ventures in the SBIR program and recognizes the exclusion from affiliation afforded to joint ventures between a protégé firm and its SBA-approved mentor, it does not specifically apply SBA's general size requirements for joint ventures to the SBIR program. The proposed rule would merely apply the general size rule for joint ventures to the SBIR program. In other words, a joint venture for an SBIR award would be considered a small business provided each partner to the joint venture, including its affiliates, meets the applicable size standard. In the case of the SBIR program, this means that each partner does not have more than 500 employees.

Section 121.1001

The rule proposes to provide authority to SBA's Associate General Counsel for Procurement Law to independently initiate or file a size protest, where appropriate.

Sections 121.1004, 125.28, 126.801, and 127.603

The proposed rule would add clarifying language to § 121.1004, § 125.28, § 126.801, and § 127.603 regarding size and/or socioeconomic status protests in connection with orders issued against a MAC. Currently, the provisions authorize a size protest where an order is issued against a MAC if the contracting officer requested a recertification in connection with that order. The proposed rule specifically authorizes a size protest relating to an order issued against a MAC where the order is set-aside for small business and the underlying MAC was awarded on an unrestricted basis, except for orders or Blanket Purchase Agreements issued under any FSS contract. The proposed rule also specifically authorizes a socioeconomic protest relating to set-aside orders based on a different socioeconomic status from the underlying set-aside MAC.

Section 121.1103

An explanation of the change is provided with the explanation for § 134.318.

Section 124.3

In response to concerns raised to SBA by several Program Participants, the proposed rule would add a definition of what a follow-on requirement or contract is. Whether a procurement requirement may be considered a follow-on procurement is important in several contexts related to the 8(a) BD program. First, SBA's regulations provide that where a procurement is awarded as an 8(a) contract, its follow-on or renewable acquisition must remain in the 8(a) BD program unless SBA agrees to release it for non-8(a) competition. 13 CFR 124.504(d)(1). SBA's regulations also require SBA to conduct an adverse impact analysis when accepting requirements into the 8(a) BD program. However, an adverse impact analysis is not required for follow-on 8(a) acquisitions or new requirements. 13 CFR 124.504(c). Finally, SBA's regulations provide that once an applicant is admitted to the 8(a) BD program, it may not receive an 8(a) sole source contract that is a follow-on procurement to an 8(a) contract that was performed immediately previously by another Participant (or former Participant) owned by the same tribe, ANC, Native Hawaiian Organization (NHO), or CDC. 13 CFR 124.109(c)(3)(ii), 124.110(e) and 124.111(d).

In order to properly assess what each of these regulations requires, the rule proposes to define the term ''follow-on requirement or contract''. The definition provides the determination considerations for whether a particular procurement is a follow-on requirement or contract: (1) Whether the scope has changed significantly, requiring meaningful different types of work or different capabilities; (2) whether the magnitude or value of the requirement has changed by at least 25 percent; and (3) whether the end user of the requirement has changed. As a general guide, if the procurement satisfies at least one of these three conditions, it may be considered a new requirement. Conversely, if the procurement satisfies none of these conditions, it is considered a follow-on procurement. However, with respect to a change in the value or magnitude of the requirement, SBA intends the 25% amount to be a guide, and not necessarily dispositive of whether a requirement qualifies as ''new.'' Applying the 25 percent rule contained in this definition rigidly could permit procuring agencies and entity-owned firms to circumvent the intent of release, sister company restriction, and adverse impact rules.

For example, a procuring agency may argue that two procurement requirements that were previously awarded as individual 8(a) contracts can be removed from the 8(a) program without requesting release from SBA because the value of the combined requirement would be at least 25 percent more than the value of either of the two previously awarded individual 8(a) contracts, and thus would be considered a new requirement. This application of the new requirement definition would permit an agency to remove two requirements from the 8(a) BD program without requesting and receiving SBA's permission for release from the program. We believe that would be inappropriate and that a procuring agency must seek SBA's approval to release the two procurements previously awarded through the 8(a) BD program. Likewise, if an entity-owned 8(a) Participant previously performed two sole source 8(a) contracts and a procuring agency sought to offer a sole source requirement to the 8(a) BD program on behalf of another Participant owned by the same entity (tribe, ANC, NHO, or CDC) that, in effect, was a consolidation of the two previously awarded 8(a) procurements, we believe it would be inappropriate for SBA to accept the offer on behalf of the sister company. Similarly, if a small business concern previously performed two requirements outside the 8(a) program and a procuring agency wanted to combine those two requirements into a larger requirement to be offered to the 8(a) program, SBA should perform an adverse impact analysis with respect to that small business even though the combined requirement had a value that was greater than 25 percent of either of the previously awarded contracts.

Section 124.105

The proposed rule would amend § 124.105(g) to provide more clarity regarding situations in which an applicant has an immediate family member that has used his or her disadvantaged status to qualify another current or former Participant. The purpose of the immediate family member restriction is to ensure that one individual does not unduly benefit from the 8(a) BD program by participating in the program beyond nine years, albeit through a second firm. This most often happens when a second family member in the same or similar line of business seeks 8(a) BD certification. However, it is not necessarily the type of business which is a problem, but, rather, the involvement in the applicant firm of the family member that previously participated in the program. The current regulatory language requires an applicant firm to demonstrate that ''no connection exists'' between the applicant and the other current or former Participant. SBA believes that requiring no connections is a bit extreme. If two brothers own two totally separate businesses, one as a general construction contractor and one as a specialty trade construction contractor, in normal circumstances it would be completely reasonable for the brother of the general construction firm to hire his brother's specialty trade construction firm to perform work on contracts that the general construction firm was doing. Unfortunately, if either firm was a current or former Participant, SBA's current regulations would prohibit SBA from certifying the second firm for participation in the program, even if the general construction firm would pay the specialty trade firm the exact same rate that it would have to pay to any other specialty trade construction firm. SBA does not believe that makes sense. An individual should not be required to avoid all contact with the business of an immediate family member. He or she should merely have to demonstrate that the two businesses are truly separate and distinct entities.

To this end, the rule proposes that an individual would not be able to use his or her disadvantaged status to qualify a concern for participation in the 8(a) BD program if that individual has an immediate family member who is using or has used his or her disadvantaged status to qualify another concern for the 8(a) BD program and the concerns are connected by any common ownership or management, regardless of amount or position, or the concerns have a contractual relationship that was not conducted at arm's length. In the first instance, if one of the two family members (or business entities owned by the family member) owned *any* portion of the business owned by the other family member, the second in time family member could not qualify his or her business for the 8(a) BD program. Similarly, if one of the two family members had any role as a director, officer or key employee in the business owned by the other family member, the second in time family member could not qualify his or her business for the 8(a) BD program. In the second instance, the second in time family member could not qualify his or her business for the 8(a) BD program if it received or gave work to the business owned by the other

family member at other than fair market value. With these changes, SBA believes that the proposed rule more accurately captures SBA's intent not to permit one individual from unduly benefitting from the program, while at the same time permitting normal business relations between two firms. SBA specifically requests comments on this provision.

The proposed rule would also amend the 8(a) BD change of ownership requirements in § 124.105(i). First, the proposed rule would lessen the burden on 8(a) Participants seeking minor changes in ownership by providing that prior SBA approval is not needed where a previous owner held less than a 20 percent interest in the concern both before and after the transaction. This would be a change from the current requirement which allows a Participant to change its ownership without SBA's prior approval where the previous owner held less than a 10 percent interest. This change from 10 percent to 20 percent would permit Participants to make minor changes in ownership more frequently without requiring them to wait for SBA approval. It would also be consistent with other changes SBA has made to reduce burdens on 8(a) applicants and Participants. For example, in 2016, SBA changed the percentage amount related to the requirement that individuals owning a certain percent of the business concern must demonstrate good character from 10 percent to 20 percent (*see* 81 FR 48580). This proposed revision would be consistent with that change and would also eliminate additional burdens on an 8(a) applicant or Participant relating to owners holding between 10 and 20 percent interest.

In addition, the proposed rule would also eliminate the requirement that all changes of ownership affecting the disadvantaged individual or entity must receive SBA prior approval before they can occur. Specifically, proposed revisions to § 124.105(i)(2) would provide that prior SBA approval is not needed where the disadvantaged individual (or entity) in control of the Participant will increase the percentage of his or her (its) ownership interest. SBA believes that prior approval is not needed in such a case because there could be no question as to whether the Participant continues to meet the program's ownership and control requirements. Again, this proposed change would decrease the amount of times and the time spent by Participant firms seeking SBA approval of a change in ownership. SBA would nevertheless continue to review all changes in ownership for which prior approval is not required, including those contemplated by the proposed rule, to ensure that the transfer was fair and equitable to the disadvantaged individual(s) (or entity) and has not unduly benefited non-disadvantaged parties to the transaction. Where SBA has determined that a change in ownership does not meet such requirements, the Agency may, in its discretion, require remedial action or initiate an appropriate adverse action, such as program suspension or termination.

Section 124.109

In order to eliminate confusion, the proposed rule would clarify several provisions relating to tribally-owned 8(a) applicants and Participants. First, SBA proposes to amend § 124.109(a)(7) and § 124.109(c)(3)(iv) to clarify that a Participant owned by an ANC or tribe need not request a change of ownership from SBA where the ANC or tribe merely reorganizes its ownership of a Participant in the 8(a) BD program by inserting or removing a wholly-owned business entity between the ANC/tribe and the Participant. SBA believes that a tribe or ANC should be able to replace one wholly-owned intermediary company with another without going through the change of ownership process and obtaining prior SBA approval. In each of these cases, SBA believes that the underlying ownership of the Participant is not changing substantively and that requiring a Participant to request approval from SBA is unnecessary. The recommendation and approval process for a change of ownership can take several months, so this change would relieve Participants owned by tribes and ANCs from this unnecessary burden and allow them to proactively conduct normal business operations without interruption.

Second, the proposed rule would amend § 124.109(c)(3)(ii) to clarify the rules pertaining to a tribe/ANC owning more than one Participant in the 8(a) BD program. The proposed rule would add two subparagraphs and an example to § 124.109(c)(3)(ii) for ease of use and understanding. In addition, SBA would clarify that if the primary NAICS code of a tribally-owned Participant is changed pursuant to § 124.112(e), the tribe could then submit an application to qualify another of its firms for participation in the 8(a) BD program under the primary NAICS code that was previously held by the Participant whose primary NAICS code was changed. A change in a primary NAICS code under § 124.112(e) should occur only where SBA has determined that the greatest portion of a Participant's revenues for the past three years are in a NAICS code other than the one identified as its primary NAICS code. In such a case, SBA has determined that in effect the second NAICS code really has been the Participant's primary NAICS code for the past three years. SBA's rules have historically provided that a Tribe or ANC may not own 51% or more of another firm which, either at the time of application or within the previous two years, has been operating in the 8(a) program under the same primary NAICS code as the applicant. Thus, this proposed rule will clarify that when SBA has changed the primary NAICS code change for a Participant, SBA has determined that first NAICS code was not the Participant's primary NAICS code for the last two years, and the tribe/ANC would be permitted to have another of its firms apply to and be admitted to the 8(a) BD program under the former primary NAICS code of the sister company.

Finally, the proposed rule would clarify the 8(a) BD program admission requirements governing how a tribally-owned applicant may demonstrate that it possesses the necessary potential for success. SBA's regulations currently permit the tribe to make a firm written commitment to support the operations of the applicant concern to demonstrate a tribally-owned firm's potential for success. Due to the increased trend of tribes establishing tribally-owned economic development corporations to oversee tribally owned businesses, SBA recognizes that in some circumstances it may be adequate to accept a letter of support from the tribally-owned economic development company rather than the tribal leadership. SBA also recognizes that in most cases, tribes are not establishing these economic development corporations as Section 17 corporations, which SBA has previously determined should be treated as an arm of the tribe and thus, the tribe itself for purposes of the 8(a) BD regulations. Rather, these corporations are often tribally owned holding companies that have been delegated authority to oversee tribal economic development and tribal business ventures. In response, this proposed rule would permit a tribally-owned applicant to satisfy the potential for success requirements by submitting a letter of support from a tribally-owned economic development corporation or other relevant tribally-owned holding company. In order for a letter of support from the tribally owned holding company to be sufficient, there must be sufficient evidence that the tribally-owned holding company has the financial resources to support the

applicant and that the tribally-owned company is controlled by the tribe.

Section 124.110

The proposed rule would make some of the same changes to § 124.110 for applicants and Participants owned and controlled by NHOs as it would to § 124.109 for tribally-owned applicants and Participants. Specifically, the proposed rule would subdivide § 124.110(e) for ease of use and understanding and would clarify that if the primary NAICS code of an NHO-owned Participant is changed pursuant to § 124.112(e), the NHO could submit an application and qualify another firm owned by the NHO for participation in the 8(a) BD program under the NAICS code that was the previous primary NAICS code of the Participant whose primary NAICS code was changed.

Section 124.111

The proposed rule would make the same change for CDCs and CDC-owned firms as for tribes and ANCs mentioned above. It would clarify that a Participant owned by a CDC need not request a change of ownership from SBA where the CDC merely reorganizes its ownership of a Participant in the 8(a) BD program by inserting or removing a wholly-owned business entity between the CDC and the Participant. It would also subdivide the current subparagraph (d) into three smaller paragraphs for ease of use and understanding, and would clarify that if the primary NAICS code of a CDC-owned Participant is changed pursuant to § 124.112(e), the CDC could submit an application and qualify another firm owned by the CDC for participation in the 8(a) BD program under the NAICS code that was the previous primary NAICS code of the Participant whose primary NAICS code was changed.

Section 124.112

SBA proposes to amend § 124.112(d)(5) regarding excessive withdrawals in connection with entity-owned 8(a) Participants. There has been some confusion as to whether an 8(a) Participant that is owned at least 51% by a tribe, ANC, NHO or CDC can make a distribution to a non-disadvantaged individual that exceeds the applicable excessive withdrawal limitation dollar amount if it is made as part of a pro rata distribution to all shareholders. SBA believes that it generally should be able to do so. Through a pro rata distribution, the only way that an entity-owned firm can increase its distribution to the tribe, ANC, NHO or CDC is if it also increases the distribution to the non-entity owner. Since the intent is to increase the distribution to the tribe, ANC, NHO or CDC, and thus increase the benefits flowing back to the community, SBA believes this serves the purposes of the program. The rule also proposes, however, that SBA could deem the distributions excessive if SBA determines that they would adversely affect the business development of the Participant.

In 2016, SBA amended § 124.112(e) to implement procedures to allow SBA to change the primary NAICS code of a Participant where SBA determined that the greatest portion of the Participant's total revenues during a three-year period have evolved from one NAICS code to another. 81 FR 48558, 48581 (July 25, 2016). The procedures require SBA to notify the Participant of its intent to change the Participant's primary industry classification and afford the Participant the opportunity to submit information explaining why such a change would be inappropriate. Several individuals have asked SBA to permit an appeal process, whereby a Participant whose primary NAICS code was changed by its servicing district office could seek further review of that determination at a different level. After hearing this concern repeated several times at the tribal consultations conducted by SBA, this proposed rule would authorize such an appeal process.

Section 124.201

This proposed rule does not amend § 124.201. However, SBA is considering adding a provision that would require a small business concern that seeks to apply for participation in the 8(a) BD program to first take an SBA-sponsored preparatory course regarding the requirements and expectations of the 8(a) BD program. SBA specifically requests comments on such a requirement.

Section 124.203

Section 124.203 requires applicants to the 8(a) BD program to submit certain specified supporting documentation, including financial statements, copies of signed Federal personal and business tax returns and individual and business bank statements. In 2016, SBA removed the requirement that an applicant must submit a signed Internal Revenue Service (IRS) Form 4506T, Request for Copy or Transcript of Tax Form, in all cases. 81 FR 48558, 48569 (July 25, 2016). At that time, SBA agreed with a commenter to the proposed rule that questioned the need for every applicant to submit IRS Form 4506T. In eliminating that requirement for every applicant, SBA reasoned that it always has the right to request any applicant to submit specific information that may be needed in connection with a specific application. As long as SBA's regulations clearly provide that SBA may request any additional documents SBA deems necessary to determine whether a specific applicant is eligible to participate in the 8(a) BD program, SBA will be able to request that a particular firm submit IRS Form 4506T where SBA believes it to be appropriate. This proposed rule would amend § 124.203 to add back the requirement that every applicant to the 8(a) BD program submit IRS Form 4506T (or when available, IRS Form 4506C). SBA believes that not having that Form readily available when needed has unduly delayed the application process for those affected applicants. In addition, SBA believes that requiring Form 4506T in every case will serve as a deterrent to firms that may think it is not necessary to fully disclose all necessary financial information. Although SBA does not often use IRS Form 4506T to verify an applicant's information, SBA believes that this additional requirement imposes a minimal burden on 8(a) BD program applicants. Additionally, SBA believes that the collection of Form 4506T will help to maintain the integrity of the program.

Section 124.204

SBA proposes to suspend the time to process an 8(a) application where SBA requests clarifying, revised or other information from the applicant. While SBA is waiting on the applicant to provide clarifying or responsive information, the Agency is not continuing to process the application.

Section 124.207

The proposed rule would amend § 124.207 to allow a concern that has been declined for 8(a) BD program participation to submit a new application 90 days after the date of the Agency's final decision to decline. This would change the current rule which requires a concern to wait 12 months from the date of the final agency decision to reapply, and would make the 8(a) BD program consistent with the HUBZone program. *See* 13 CFR 126.309. SBA believes that this change would reduce the number of appeals to SBA's Office of Hearings and Appeals (OHA) and greatly reduce the costs associated with appeals borne by disappointed applicants. If a firm can correct the deficiencies in its initial application and reapply within 90 days, it may be much more likely to forego appealing to OHA, where the process can take 90 days or

more for resolution. Because a firm that is declined could submit a new application 90 days after the decline decision, SBA requests comments on whether the current reconsideration process should be eliminated.

Section 124.300 and 124.301

The proposed rule would redesignate the current § 124.301 (which discusses the various ways a business may leave the 8(a) BD program) as § 124.300 and add a new § 124.301 to specifically enunciate the voluntary withdrawal and early graduation procedures. The rule would set forth SBA's current policy that a Participant may voluntarily withdraw from the 8(a) BD program at any time prior to the expiration of its program term. In addition, where a Participant believes it has substantially achieved the goals and objectives set forth in its business plan, SBA would allow the Participant to elect to voluntarily early graduate from the 8(a) BD program. That too is SBA's current policy, and the proposed rule merely captures it in SBA's regulations.

The proposed rule would, however, change the level at which voluntary withdrawal and voluntary early graduation could be finalized by SBA. Currently, a firm submits its request to voluntarily withdraw or early graduate to its servicing SBA district office. Once the district office concurs, the request is sent to the Associate Administrator for Business Development (AA/BD) for final approval. SBA believes that requiring several layers of review to permit a concern to voluntarily exit the 8(a) BD program is unnecessary. Because an entity cannot have a second firm admitted to the 8(a) BD program with the same primary NAICS code as a sister company for a period of two years from the date that the sister company left the program, requiring firms to wait a potentially significant amount of time for several layers of SBA reviewers to approve a voluntary withdrawal or voluntary early graduation action could adversely impact the overall business operations of the entity and other concerns owned by the entity. Thus, the rule proposes that a Participant must still request voluntary withdrawal or voluntary early graduation from its servicing district office, but the action would be complete once the District Director recognizes the voluntary withdrawal or voluntary early graduation. SBA believes this would eliminate unnecessary delay in processing these actions.

Section 124.304

The proposed rule would clarify the effect of a decision made by the AA/BD to terminate or early graduate a Program Participant. Under SBA's current procedures, once the AA/BD renders a decision to early graduate or terminate a Participant from the 8(a) BD program, the affected Participant has 45 days to appeal that decision to SBA's OHA. If no appeal is made, the AA/BD's decision becomes the final agency decision after that 45-day period. If the Participant appeals to OHA, the final agency decision will be the decision of the administrative law judge at OHA. There has been some confusion as to what the effect of the AA/BD decision is pending the decision becoming the final agency decision. The proposed rule clarifies that where the AA/BD issues a decision terminating or early graduating a Participant, SBA would treat the firm as being suspended. SBA does not believe that it would not make sense to allow a Participant to continue to receive program benefits after the AA/BD has terminated or early graduated the firm from the program. If OHA ultimately overrules the AA/BD decision, the suspension would be lifted and the length of the suspension would be added to the Participant's program term.

Sections 124.305 and 124.402

Section 124.402 requires each firm admitted to the 8(a) BD program to develop a comprehensive business plan and to submit that business plan to SBA. Currently, § 124.402(b) provides that a newly admitted Participant must submit its business plan to SBA as soon as possible after program admission and that the Participant will not be eligible for 8(a) BD benefits, including 8(a) contracts, until SBA approves its business plan. Several firms have complained that they missed contract opportunities because SBA did not approve their business plans before procuring agencies sought to award contracts to fulfill certain requirements. While SBA continues to believe that it is important for a newly admitted Participant to submit its business plan to SBA as expeditiously as possible, SBA also understands the adverse consequences that can ensue if a firm loses an opportunity that it has lined up because its business plan is not approved prior to the time that a procuring agency seeks to fulfill a particular procurement requirement. In response, the proposed rule would amend § 124.402(b) to eliminate the provision that a Participant cannot receive any 8(a) BD benefits until SBA has approved its business plan. A firm coming in to the 8(a) BD program with commitments from one or more procuring agencies could immediately be awarded one or more 8(a) contracts. Instead, the proposed rule would provide that SBA would suspend a Participant from receiving 8(a) BD program benefits if it has not submitted its business plan to the servicing district office and received SBA's approval within 60 days after program admission. SBA believes that firms coming into the 8(a) BD program possessing the potential for success required for program entry would most likely have business plans in place and should be able to have their business plans approved by SBA within 60 days of program admission. If that cannot happen within 60 days, SBA would suspend the Participant's business plan under the proposed changes to § 124.305(h). This would freeze a firm's program term, and a firm would not lose any time in the program.

The proposed rule would also correct a typographical error contained in § 124.305(h)(1)(ii). Under § 124.305(h)(1)(ii), an 8(a) Participant can elect to be suspended from the 8(a) program where a disadvantaged individual who is involved in controlling the day-to-day management and control of the Participant is called to active military duty by the United States. Currently, the regulation states that the Participant may elect to be suspended where the individual's participation in the firm's management and daily business operations is critical to the firm's continued eligibility, and the Participant elects not to designate a non-disadvantaged individual to control the concern during the call-up period. That should read where the Participant elects not to designate another disadvantaged individual to control the concern during the call-up period. It was not SBA's intent to allow a non-disadvantaged individual to control the firm during the call-up period and permit the firm to continue to be eligible for the program.

Sections 124.501 and 124.507

Section 124.501 is entitled ''What general provisions apply to the award of 8(a) contracts?'' SBA must determine that a Participant is eligible for the award of both competitive and sole source 8(a) contracts. However, the requirement that SBA determine eligibility is currently contained specifically only in the 8(a) competitive procedures at § 124.507(b)(2). Although SBA determines eligibility for sole source 8(a) awards at the time it accepts a requirement for the 8(a) BD program, that process is not specifically stated in the regulations. The proposed rule would move the eligibility determination procedures for

competitive 8(a) contracts from § 124.507(b)(2) to the general provisions of § 124.501 and would specifically address eligibility determinations for sole source 8(a) contracts. To accomplish this, the proposed rule would revise current § 124.501(g).

Similarly, SBA believes that the provisions requiring a bona fide place of business within a particular geographic area for 8(a) construction awards should also appear in the general provisions applying to 8(a) contracts set forth in § 124.501. Section 8(a)(11) of the Small Business Act, 15 U.S.C. 637(a)(11), requires that to the maximum extent practicable 8(a) construction contracts ''shall be awarded within the county or State where the work is to be performed.'' SBA has implemented this statutory provision by requiring a Participant to have a bona fide place of business within a specific geographic location. Currently, the bona fide place of business rules appear only in the procedures applying to competitive 8(a) procurements in § 124.507(c)(2). The proposed rule would move those procedures to a new § 124.501(k), which would clearly make them applicable to both sole source and competitive 8(a) awards. Based on the statutory language, SBA believes that the requirement to have a bona fide place of business in a particular geographic area currently applies to both sole source and competitive 8(a) procurements, but moving the requirement to the general applicability section would remove any doubt or confusion.

In response to concerns raised by Participants, the proposed rule would also impose time limits within which SBA district offices should process requests to add a bona fide place of business. SBA has heard that several Participants missed out on 8(a) procurement opportunities because their requests for SBA to verify their bona fide places of business were not timely processed. In order to alleviate this perceived problem, the proposed rule would provide that in connection with a specific 8(a) competitive solicitation, the reviewing office will make a determination whether or not the Participant has a bona fide place of business in its geographical boundaries within 5 working days of a site visit or within 15 working days of its receipt of the request from the servicing district office if a site visit is not practical in that timeframe. SBA requests comments on whether a Participant that has filed a request to have a bona fide place of business recognized by SBA in time for a particular 8(a) construction procurement may submit an offer for that procurement where it has not received a response from SBA before the date offers are due. In other words, should a Participant that has requested the recognition of a bona fide place of business beyond the time limits set forth in this proposed rule be able to presume approval and submit an offer as an eligible Participant? SBA does not want to harm Participants that truly have set up bona fide places of business, but at the same time does not want to give eligibility to firms that have not met the requirements necessary to establish a bona fide place of business.

Section 124.503

Currently, § 124.503(g) provides that a Basic Ordering Agreement (BOA) is not a contract under the FAR. Rather, each order to be issued under the BOA is an individual contract. As such, a procuring activity must offer, and SBA must accept, each task order under a BOA in addition to offering and accepting the BOA itself. Once a Participant leaves the 8(a) BD program or otherwise becomes ineligible for future 8(a) contracts (*e.g.,* becomes other than small under the size standard assigned to a particular contract) it cannot receive further 8(a) orders under a BOA. Similarly, a blanket purchase agreement (BPA) is also not a contract. A BPA (whether a BPA under part 13 of the Federal Acquisition Regulation (FAR) or a BPA under subpart 8.4 of the FAR)) is not a contract because it neither obligates funds nor requires placement of any orders against it. Instead, it is an understanding between an ordering agency and a contractor that allows the agency to place future orders more quickly by identifying terms and conditions applying to those orders, a description of the supplies or services to be provided, and methods for issuing and pricing each order. The government is not obligated to place any orders, and either party may cancel a BPA at any time.

Although current § 124.503(g) addresses BOAs, it does not specifically mention BPAs. The proposed rule would amend § 124.503 to merely specifically recognize that BPAs are also not contracts and should be afforded the same treatment as BOAs.

Section 124.504

This rule also proposes to make several changes to § 124.504.

The proposed rule would amend § 124.504(b) to alter the provision prohibiting SBA from accepting a requirement into the 8(a) BD program where a procuring activity competed a requirement among 8(a) Participants prior to offering the requirement to SBA and receiving SBA's formal acceptance of the requirement. SBA believes that the restriction as written is overly harsh and burdensome to procuring agencies. Several contracting officers have not offered a follow-on procurement to the 8(a) program prior to conducting a competition restricted to eligible 8(a) Participants because they believed that as a follow-on it must be procured through the 8(a) program. They issued solicitations identifying them as competitive 8(a) procurements, selected an apparent successful offeror and then sought SBA's eligibility determination prior to making an award. A strict interpretation of the current regulatory language would prohibit SBA from accepting such a requirement. Such an interpretation could seriously adversely affect an agency's procurement strategy by unduly delaying the award of a contract. That was never SBA's intent. As long as a procuring agency clearly identified a requirement as a competitive 8(a) procurement and the public fully understood it to be restricted only to eligible 8(a) Participants, SBA should be able to accept that requirement regardless of when the offering occurred.

The rule would clarify SBA's intent regarding the requirement that a procuring agency must seek and obtain SBA's concurrence to release any follow-on procurement from the 8(a) BD program. This is not a change in policy, but rather a clarification of SBA's current policy and the position SBA has taken in several protests before the General Accountability Office. Some agencies have attempted to remove a follow-on procurement from the 8(a) program and reprocure the requirement through a MAC or Government-wide Acquisition Contract (GWAC) that is not an 8(a) contract without seeking release by saying that they intend to issue a competitive 8(a) order off the MAC or GWAC. In other words, because the order off the MAC or GWAC would be offered to and accepted for award through the 8(a) BD program and the follow-on work would be performed through the 8(a) BD program, some procuring agencies believe that release is not needed. SBA does not agree. In such a case, the underlying contract is not an 8(a) contract. The procuring agency is attempting to remove a requirement from the 8(a) program to a contract that is not an 8(a) contract. That is precisely what release is intended to apply to. Moreover, because § 124.504(d)(4) provides that the requirement to seek release of an 8(a) requirement from SBA does not apply to orders offered to and accepted for the 8(a) program where the underlying MAC

or GWAC is not itself an 8(a) contract, allowing a procuring agency to move an 8(a) contract to an 8(a) order off a non-8(a) contract vehicle would allow the procuring agency to then remove the next follow-on to the 8(a) order out of the 8(a) program entirely without any input from SBA. A procuring agency could take an 8(a) contract with a base year and four one-year option periods, turn it into a one-year 8(a) order off a non-8(a) contract vehicle, and then remove it from the 8(a) program entirely after that one-year performance period. That was certainly not the intent of SBA's regulations. As such, this rule clarifies that the request for and granting of a release of a follow-on procurement from the 8(a) BD program is required when the procurement will be moved out of the 8(a) BD program as an independent contract into a MAC or GWAC. SBA has received additional comments recommending that release should also apply even if the underlying pre-existing MAC or GWAC to which a procuring agency seeks to move a follow-on requirement is itself an 8(a) contract. These commenters argue that an 8(a) incumbent contractor may be seriously hurt by moving a procurement from a general 8(a) competitive procurement to an 8(a) MAC or GWAC to which the incumbent is not a contract holder. In such a case, the incumbent would have no opportunity to win the award for the follow-on contract, and, without the release process, would have no opportunity to demonstrate that it would be adversely impacted or to try to dissuade SBA from agreeing to release the procurement. In response, the proposed rule would provide that SBA must agree to release any follow-on requirement where a procuring agency seeks to reprocure that requirement through a limited contracting vehicle which is not available to all 8(a) BD Program Participants (*e.g.,* any multiple award or Governmentwide acquisition contract, whether or not the underlying MAC or GWAC is itself an 8(a) contract). If an agency seeks to reprocure a current 8(a) requirement as a competitive 8(a) award for a new 8(a) MAC or GWAC vehicle, SBA's concurrence would not be required because such a competition would be available to all 8(a) BD Program Participants.

The proposed rule would also clarify that in all cases where a procuring agency seeks to fulfill a follow-on requirement outside of the 8(a) BD program, except where it is statutorily or otherwise required to use a mandatory source (*see* FAR subpart 8.6 and 8.7), it must make a written request to and receive the concurrence of SBA to do so. In such a case, the proposed rule would require a procuring agency to notify SBA that it will take a follow-on procurement out of the 8(a) procurement because of a mandatory source. Such notification would be required at least 30 days before the end of the contract period to give the 8(a) Participant the opportunity to make alternative plans.

In addition, SBA does not typically consider the value of a bridge contract when determining whether an offered procurement is a new requirement. A bridge contract is meant to be a temporary stop-gap measure intended to ensure the continuation of service while an agency finalizes a long-term procurement approach. As such, SBA does not typically consider a bridge contract as part of the new requirement analysis, unless there is some basis to believe that the agency is altering the duration of the option periods to avoid particular regulatory requirements. Whether to consider the bridge contract is determined on a case-by-case basis given the facts of the procurement at issue. SBA seeks comments as to whether this long-standing policy should also be incorporated into the regulations.

Section 124.509

The proposed rule would revise § 124.509(e), regarding how a Participant can obtain a waiver to the requirement prohibiting it from receiving further sole source 8(a) contracts where the Participant does not meet its applicable non-8(a) business activity target. Currently, the regulations require the AA/BD to process a Participant's request for a waiver in every case. The proposed rule would substitute SBA for the AA/BD to allow flexibility to SBA to determine the level of processing in a standard operating procedure outside the regulations. SBA believes that at least at some level, the district office should be able to process such requests for waiver. That correct level could be any requirement below the Simplified Acquisition Threshold (SAT), or maybe some other specific dollar value. Putting such a requirement in an SOP, instead of the regulations, however, would give flexibility to SBA to adjust the requirement as necessary, and allow more straightforward requests to be processed more expeditiously.

The current regulation also requires the SBA Administrator on a non-delegable bases to decide requests for waiver from a procuring agency. In other words, if the Participant itself does not request a waiver to the requirement prohibiting it from receiving further sole source 8(a) contracts, but an agency does because it believes that the award of a sole source contract to the identified Participant is needed to achieve significant interests of the Government, the SBA Administrator must currently make that determination. Requiring such a request to be processed by several levels of SBA reviewers and then by the Administrator slows down the processing. If a procuring agency truly needs something quickly, it could be harmed by the processing time. The proposed rule would change the Administrator from making these determinations to SBA. This should allow these requests to be processed more quickly.

Section 124.513

Currently, § 124.513(e) provides that SBA must approve a joint venture agreement prior to the award of an 8(a) contract on behalf of the joint venture. This requirement applies to both competitive and sole source 8(a) procurements. SBA does not approve joint venture agreements in any other context, including a joint venture between an 8(a) Participant and its SBA-approved mentor (which may be other than small) in connection with a non-8(a) contract (*i.e.,* small business set-aside, HUBZone, SDVO small business, or WOSB contract). In order to be considered an award to a small disadvantaged business (SDB) for a non-8(a) contract, a joint venture between an 8(a) Participant and a non-8(a) Participant must be controlled by the 8(a) partner to the joint venture and otherwise meet the provisions of § 124.513(c) and (d). If the non-8(a) partner to the joint venture is also a small business under the size standard corresponding to the NAICS code assigned to the procurement, the joint venture could qualify as small if the provisions of § 124.513(c) and (d) were not met (*see* § 121.103(h)(3)(i), where a joint venture can qualify as small as long as each party to the joint venture individually qualifies as small), but the joint venture could not qualify as an award to an SDB in such case. If the joint venture were between an 8(a) Participant and its large business mentor, the joint venture could not qualify as small if the provisions of § 124.513(c) and (d) were not met. The size of a joint venture between a small business protégé and its large business mentor is determined without looking at the size of the mentor only when the joint venture complies with SBA's regulations regarding control of the joint venture. Where another offeror believes that a joint venture between a protégé and its large business mentor has not

complied with the applicable control regulations, it may protest the size of the joint venture. The applicable Area Office of SBA's Office of Government Contracting would then look at the joint venture agreement to determine if the small business is in control of the joint venture within the meaning of SBA's regulations. If that Office determines that the applicable regulations were not followed, the joint venture would lose its exclusion from affiliation, be found to be other than small, and, thus, ineligible for an award as a small business. This size protest process has worked well in ensuring that small business joint venture partners do in fact control non-8(a) contracts with their large business mentors. Because size protests are authorized for competitive 8(a) contracts, SBA and believes that the size protest process could work similarly for competitive 8(a) contracts. As such, this proposed rule would eliminate the need for 8(a) Participants to seek and receive approval from SBA of every joint venture for competitive 8(a) contracts. SBA believes that this would significantly lessen the burden imposed on 8(a) small business Participants. Participants would not be required to submit additional paperwork to SBA and would not have to wait for SBA approval in order to seek competitive 8(a) awards.

However, the proposed rule would not eliminate the requirement that SBA must approve joint ventures in connection with sole source 8(a) awards. Because size protests from other Participants are not permitted with respect to sole source 8(a) procurements, there would be no way to ensure that a joint venture for an 8(a) sole source contract between an 8(a) Participant and its large business mentor is controlled by the 8(a) Participant and otherwise meets SBA's joint venture requirements if SBA did not continue to look at joint ventures in that context. SBA believes that it is important to ensure that the joint venture rules would continue to be followed, and without any other enforcement mechanism, SBA must continue to approve joint ventures for 8(a) sole source contracts. The only other alternative approach would be to allow size protests in connection with sole source 8(a) contracts, but SBA believes that is not appropriate because other Participants are not really interested parties with respect to a sole source 8(a) procurement offered to the 8(a) program on behalf of another Participant.

Section 124.519

Section 124.519 limits the ability of 8(a) Participants to obtain additional sole source 8(a) contracts once they have reached a certain dollar level of overall 8(a) contracts. Currently, for a firm having a receipts-based size standard corresponding to its primary NAICS code, the limit above which a Participant can no longer receive sole source 8(a) contracts is five times the size standard corresponding to its primary NAICS code, or $100,000,000, whichever is less. For a firm having an employee-based size standard corresponding to its primary NAICS code, the limit is $100,000,000. In order to simplify this requirement, this proposed rule would provide that a Participant may not receive sole source 8(a) contract awards where it has received a combined total of competitive and sole source 8(a) contracts in excess of $100,000,000 during its participation in the 8(a) BD program, regardless of its primary NAICS code. In addition, the rule would clarify that in determining whether a Participant has reached the limit identified in paragraph (a) of this section, SBA would look at the 8(a) revenues a Participant has actually received, not projected 8(a) revenues that a Participant might receive through an indefinite delivery or indefinite quantity contract, a multiple award contract, or options or modifications. Finally, the proposed rule would amend what types of small dollar value 8(a) contracts should not be considered in determining whether a Participant has reached the 8(a) revenue limit. Currently, SBA does not consider 8(a) contracts awarded under $100,000 in determining whether a Participant has reached the '1 8(a) revenue limit. The proposed rule would replace the $100,000 amount with a reference to the SAT. SBA has delegated to procuring agencies the ability to award sole source 8(a) contracts without offer and acceptance for contracts valued at or below the SAT. Because SBA does not accept such procurements into the 8(a) BD program, it is difficult for SBA to monitor these awards. The proposed rule would merely align the 8(a) revenue limit with that authority.

Section 125.2

The proposed rule would add a new paragraph (g) requiring contracting officers to consider the past performance and experience of first tier subcontractors in certain instances. This consideration is statutorily required for bundled or consolidated contracts (15 U.S.C. 644(e)(4)(B)(i)) and for multiple award contracts valued above a certain dollar amount that corresponds to the agency's substantial bundling threshold (15 U.S.C. 644(q)(1)(B)). Following the statutory provisions, the proposed rule requires a contracting officer to consider the past performance and experience of first tier subcontractors in those two categories of contracts. The proposed rule would not require a contracting officer to consider the past performance, capabilities and experience of each first tier subcontractor as the capabilities and past performance of the small business prime contractor in other instances. Instead, it would provide discretion to contracting officers to consider such past performance, capabilities and experience of each first tier subcontractor where appropriate. SBA specifically requests comments as to whether as a policy matter such consideration should be required in all cases, or limited only to the statutorily required instances as proposed.

Section 125.3

The Small Business Act explicitly prohibits the Government from requiring small businesses to submit subcontracting plans. 15 U.S.C. 637(d)(8). This prohibition is set forth in § 125.3(b) of SBA's regulations and in FAR 19.702(b)(1). Under the Alaska Native Claims Settlement Act (ANCSA), a contractor receives credit towards the satisfaction of its small or small disadvantaged business subcontracting goals when contracting with an ANC-owned firm. 43 U.S.C. 1626(e)(4)(B). There has been some confusion as to whether an ANC-owned firm that does not individually qualify as small but counts as a small business or a small disadvantaged business for subcontracting goaling purposes under 43 U.S.C. 1626(e)(4)(B) must itself submit a subcontracting plan. SBA believes that such a firm is not currently required to submit a subcontracting plan, but proposes to add clarifying language to § 125.3(b) to clear up any confusion. The proposed rule would make clear that all firms considered to be small businesses, whether the firm qualifies as a small business concern for the size standard corresponding to the NAICS code assigned to the contract or is deemed to be treated as a small business concern by statute, would not be required to submit subcontracting plans.

Section 125.5

The proposed rule clarifies that SBA does not use the certificate of competency (COC) procedures for 8(a) sole source contracts. This has long been SBA's policy. *See* 62 FR 43584,

43592 (Aug. 14, 1997). Instead of using SBA COC procedures, an agency that finds a potential 8(a) sole source awardee to be non-responsible should proceed through the substitution or withdrawal procedures in the proposed § 124.503(e). The proposed rule also changes the threshold for COC appeals from $100,000 to the simplified acquisition threshold.

Section 125.6

Section 125.6(b) provides guidance on which limitation on subcontracting requirement applies to a ''mixed contract.'' The section currently refers to a mixed contract as one that combines both services and supplies. SBA inadvertently did not include the possibility that a mixed contact could include construction work, although in practice SBA has applied this section to a contract requiring, for example, both services and construction work. The proposed revision would merely recognize that a mixed contract is one that integrates any combination of services, supplies, or construction. A contracting officer would then select the appropriate NAICS code, and that NAICS code is determinative as to which limitation on subcontracting and performance requirement applies.

SBA also asks for comments regarding how the nonmanufacturer rule should be applied in multiple item procurements (reference § 125.6(a)(2)(ii)). Currently, for a multiple item procurement where a nonmanufacturer waiver is granted for one or more items, compliance with the limitation on subcontracting requirement will not consider the value of items subject to a waiver. As such, more than 50% of the value of the products to be supplied by the nonmanufacturer that are not subject to a waiver must be the products of one or more domestic small business manufacturers or processors. The regulation gives an example where a contract is for $1,000,000 and calls for the acquisition of 10 items. Market research shows that nine of the items can be sourced from small business manufacturers and one item is subject to an SBA class waiver. The projected value of the item that is waived is $10,000. Under the current regulatory language, at least 50% of the value of the items not subject to a waiver, or $495,000 (50% of $990,000), must be supplied by one or more domestic small business manufacturers, and the prime small business nonmanufacturer may act as a manufacturer for one or more items. Several small business nonmanufacturers have disagreed with this provision. They believe that in order to qualify as a small business nonmanufacturer, at least 50% of the value of the contract must come from either small business manufacturers or from any businesses for items which have been granted a waiver (or that small business manufacturers plus waiver must equal at least 50%). In other words, in the above example, $500,000 (50% of the value of the contract) must come from small business manufacturers or be subject to a waiver. If items totaling $10,000 are subject to a waiver, then only $490,000 worth of items must come from small business manufacturers; requiring $5,000 less from small business manufacturers. SBA is considering changing this in the final rule, but seeks comments on whether this approach makes sense. The current approach provides added incentives for small business manufacturers. The recommended approach might cause more requirements to be set aside for small business, but SBA questions whether this would truly benefit small business if small business manufactures are not ultimately providing the products.

Section 125.8

The proposed rule would make conforming changes to § 125.8 in order to take into account merging the 8(a) BD Mentor-Protégé Program with the All Small Mentor-Protégé Program.

Proposed § 125.8(b)(2)(iv) would permit the parties to a joint venture to agree to distribute profits from the joint venture so that the small business participant(s) receive profits from the joint venture that exceed the percentage commensurate with the work performed by them. Normally, profits would be distributed commensurate with the work performed. However, several small businesses have asked SBA to allow the parties to agree to pay a small business more if they would like to do so. Of course, SBA would not permit any agreement that would pay a small business less than that corresponding to the work it performed. But, if the parties would like to distribute the profits to further benefit a small business, SBA would not want to prohibit that.

Section 125.9

The proposed rule would first reorganize some of the current provisions in § 125.9 for ease of use and understanding. Paragraph 125.9(b) would be reorganized and clarified. The proposed rule clarifies that in order to qualify as a mentor, SBA will look at three things, whether the proposed mentor: Is capable of carrying out its responsibilities to assist the protégé firm under the proposed mentor-protégé agreement; does not appear on the Federal list of debarred or suspended contractors; and can impart value to a protégé firm. Instead of requiring SBA to look at and determine that a proposed mentor possesses good character in every case, the proposed rule would amend this provision to specify that SBA will decline an application if SBA determines that the mentor does not possess good character. The proposed rule would also clarify that a mentor that has more than one protégé cannot submit competing offers in response to a solicitation for a specific procurement through separate joint ventures with different protégés. That has always been SBA's intent (the current rule specifies that a second mentor-protégé relationship cannot be a competitor of the first), but SBA wants to make this clear in response to questions SBA has received regarding this issue.

SBA is also considering whether to limit mentors only to those firms having average annual revenues of less than $100 million. Currently, any concern that demonstrates a commitment and the ability to assist small business concerns may act as a mentor. This includes large businesses of any size. SBA has received several suggestions from ''mid-size'' companies (*i.e.,* those that no longer qualify as small under their primary NAICS codes, but believe that they cannot adequately compete against the much larger companies) that a mentor-protégé program that excluded very large businesses would be beneficial to the mid-size firms and allow them to more effectively compete. SBA's focus in the mentor-protégé program is the protégé firm, what business development assistance a proposed mentor can provide to a protégé to enable that firm to more effectively compete on its own in the future. Whether a mentor is $1,000 over the size standard corresponding to its primary NAICS code or many millions of dollars over has not been a concern to SBA. SBA seeks a program that will provide the most effective business development assistance to small business protégé firms. SBA requests comments on whether the size of a mentor should be restricted in the regulations, and whether small businesses would be better or worse served by such a restriction.

The proposed rule would implement Section 861 of the National Defense Authorization Act (NDAA) of 2019, Public Law 115–232, to make three changes to the mentor-protégé program in order to benefit Puerto Rican small businesses. First, the proposed rule would amend § 125.9(b) regarding the

number of protégé firms that one mentor can have at any one time. Currently, the regulation provides that under no circumstances can a mentor have more than three protégés at one time. Section 861 of the NDAA provides that the restriction on the number of protégé firms a mentor can have shall not apply to up to two mentor-protege relationships if such relationships are with a small business that has its principal office located in the Commonwealth of Puerto Rico. As such, proposed § 125.9(b)(3)(ii) would provide that a mentor generally cannot have more than three protégés at one time, but that the first two mentor-protégé relationships between a specific mentor and a small business that has its principal office located in the Commonwealth of Puerto Rico would not count against the limit of three proteges that a mentor can have at one time. Thus, if a mentor did have two protégés that had their principal offices in Puerto Rico, it could have an additional three protégés, or a total of five protégés, and comply with SBA's requirements. The proposed rule would also add a new § 125.9(d)(6) to implement a provision of Section 861 of NDAA 2019, which authorizes contracting incentives to mentors that subcontract to protégé firms that are Puerto Rico businesses. Specifically, proposed § 125.9(d)(6) would provide that a mentor that provides a subcontract to a protégé that has its principal office located in Puerto Rico may (i) receive positive consideration for the mentor's past performance evaluation, and (ii) apply costs incurred for providing training to such protégé toward the subcontracting goals contained in the subcontracting plan of the mentor. SBA requests comments as to whether the term ''positive consideration'' can be better defined. Section 861 specifically authorizes these two incentives, but suggests that other incentives may also be appropriate. SBA also seeks comments as to whether any other contracting incentives could be feasible.

The proposed rule would clarify the requirements for a firm seeking to form a mentor-protégé relationship in a NAICS code that is not the firm's primary NAICS code (§ 125.9(c)(1)(ii)). SBA intended that a firm could be a protégé in a secondary NAICS code for which it qualifies as small if it has done work previously in that secondary NAICS code. SBA did not want a firm that had grown to be other than small in its primary NAICS codes to form a mentor-protégé relationship in a NAICS code in which it had no experience simply because it qualified as small in that other NAICS code. SBA believes that such a situation (*i.e.,* having a protégé with no experience in a secondary NAICS code) could lead to abuse of the program. It would be hard for a firm with no experience in a secondary NAICS code to be the lead on a joint venture with its mentor. Similarly, a mentor with all the experience could easily take control of a joint venture and perform all of the work required of the joint venture. The current regulation, however, has caused some confusion. It states that where a firm is other than small in its primary NAICS code, the firm can qualify as a protégé in a secondary NAICS code if it is small in that secondary NAICS code and has prior experience or previously performed work in that secondary NAICS code. Some have read this provision as permitting a mentor-protégé relationship in a secondary NAICS code only where the firm is other than small in its primary NAICS code. That was not SBA's intent. In addition, others have read this provision as requiring prior experience in a secondary NAICS code only where the firm is other than small in its primary NAICS code, but not where it qualifies as small in its primary NAICS code. This too was not SBA's intent. The proposed rule clarifies that a firm may seek to be a protégé in any NAICS code for which it qualifies as small and can form a mentor-protégé relationship in a secondary NAICS code if it qualifies as small and has prior experience or previously performed work in that NAICS code.

In addition, although SBA does not believe that a regulatory change is needed, SBA would like to clarify SBA's position on what experience a protégé firm must have if it seeks a mentor-protégé relationship in its primary NAICS code. As noted above, SBA's regulations require a firm seeking to be a protégé in a secondary NAICS code to demonstrate that it has prior experience in that secondary NAICS code. The regulation is silent with respect to a firm having experience in its primary NAICS code. Generally, a firm would have performed some work in its primary NAICS code—normally, that is how SBA determines what the firm's primary NAICS code is (*i.e.,* the code in which it has received the majority of its revenues). However, a firm owned by an entity (*i.e.,* tribe, ANC, NHO or CDC), can be admitted to the 8(a) BD without much experience in its self-identified primary NAICS code if the entity has made a firm commitment to support the operations of the applicant concern and it has the financial ability to do so. In these limited instances, where a new entity-owned 8(a) Participant seeks to form a mentor-protégé relationship, it may not have any expertise in its identified primary NAICS code. The 8(a) BD Mentor-Protégé Program has allowed mentor-protégé relationships in these circumstances. Because the 8(a) BD Mentor-Protégé Program is being merged with the All Small Mentor-Protégé Program, it follows that SBA would continue to allow such mentor-protégé relationships.

The proposed rule would also respond to concerns raised by small businesses regarding the regulatory limit of permitting only two mentor-protégé relationships even where the small business protégé receives no or limited assistance from its mentor through a particular mentor-protégé agreement. SBA has informally permitted a mentor-protégé relationship not to count against the limit of two such relationships in total where the protégé can demonstrate that it has not received any assistance from its mentor under the mentor-protégé relationship. SBA believes that a relationship that provides no business development assistance or contracting opportunities to a protégé should not be counted against the firm, or that the firm should not be restricted to having only one additional mentor-protégé relationship in such a case. SBA considered implementing in this proposed rule a provision which would formalize its previous policy—*i.e.,* to not count a mentor-protégé relationship where the protégé can demonstrate that it received no assistance from the relationship. In order to eliminate any disagreements as to whether a firm did or did not receive any assistance under its mentor-protégé agreement, this rule proposes to establish an easily understandable and objective basis for counting or not counting a mentor-protégé relationship. Specifically, the rule proposes to amend § 125.9(e)(6) to not count any mentor-protégé relationship toward a firm's two permitted lifetime mentor-protégé relationships where the mentor-protégé agreement is terminated within 18 months from the date SBA approved the agreement.

This rule also proposes to eliminate the reconsideration process for declined mentor-protégé agreements in § 125.9(f) as unnecessary. Currently, if SBA declines a mentor-protégé agreement, the prospective small business protégé may make changes to its agreement and seek reconsideration from SBA within 45 days of SBA's decision to decline the mentor-protégé relationship. The current regulations also allow the small

business to submit a new (or revised) mentor-protégé agreement to SBA at any point after 60 days from the date of SBA's final decision declining a mentor-protégé relationship. SBA believes that this ability to submit a new or revised mentor-protégé agreement after 60 days is sufficient.

Finally, the proposed rule would add clarifying language regarding the annual review of mentor-protégé relationships. It is important that SBA receive an honest assessment from the protégé of how the mentor-protégé relationship is working, whether the protégé has received the agreed-upon business development assistance, and whether the protégé would recommend the mentor to be a mentor for another small business in the future. SBA needs to know if the mentor is not providing the agreed-upon business development assistance to the protégé. This would affect that firm's ability to be a mentor in the future. The rule would also provide that if a protégé does not provide information relating to the mentor-protégé relationship, thereby hindering SBA's ability to properly evaluate the relationship, SBA may decide not to approve continuation of the mentor-protégé relationship.

SBA has also received several complaints from small business protégés whose mentor-protégé relationships were terminated by the mentor soon after a joint venture between the protégé and mentor received a Government contract as a small business. SBA considered adding additional protections for protégé firms, but is not certain how best to remedy this situation. Current § 125.9(h) provides consequences for when a mentor does not provide to the protégé firm the business development assistance set forth in its mentor-protégé agreement. Under the current regulations, where that occurs, the firm will be ineligible to again act as a mentor for a period of two years from the date SBA terminates the mentor-protégé agreement, SBA may recommend to the relevant procuring agency to issue a stop work order for each Federal contract for which the mentor and protégé are performing as a small business joint venture, and SBA may seek to substitute the protégé firm for the joint venture if the protégé firm is able to independently complete performance of any joint venture contract without the mentor. SBA believes that provision should be sufficient to dissuade mentors from early terminating mentor-protégé agreements. SBA also considered adding a provision requiring a joint venture between a protégé and its mentor to recertify its size if the mentor-protégé relationship prematurely ends. In such a case, if the mentor was an other than small business and the joint venture could not recertify as small, the procuring agency could no longer count the contract as an award to small business. SBA specifically requests comments on this alternative and seeks comments on other possible alternatives to remedy this perceived problem.

Section 125.18

In addition to the revision to § 125.18(c) identified above, the rule proposes to amend the language in § 125.18(a) to clarify what representations and certifications a business concern seeking to be awarded a SDVO contract must submit as part of its offer.

Sections 126.616 and 126.618

The proposed rule would make minor revisions to §§ 126.616 and 126.618 by merely deleting references to the 8(a) BD Mentor-Protégé Program, since that program would no longer exist as a separate program.

Sections 127.503(h) and 127.504

In addition to the revision to § 127.504(c) identified above, the rule proposed to make other changes or clarifications to § 127.504. The proposed rule would rename and revise § 127.504 for better understanding and ease of use. The section heading would be changed to ''What requirements must an EDWOSB or WOSB meet to be eligible for an EDWOSB or WOSB contract?''. The text would then more clearly define those requirements and, as identified above, add language similar to that contained in the regulations governing the other socio-economic programs.

The proposed rule would move the recertification procedures for WOSBs from § 127.503(h) to § 127.504(e).

Sections 134.318 and 121.1103

The proposed rule would amend § 134.318 to make it consistent with SBA's size regulations. In this regard, § 121.1103(c)(1)(i) of SBA's size regulations provides that upon receipt of the service copy of a NAICS code appeal, the contracting officer must ''stay the solicitation.'' However, when that rule was implemented, a corresponding change was not made to the procedural rules for SBA's OHA contained in part 134. Section 134.318(b) provides that if OHA changes a NAICS code in response to a NAICS code appeal, and the contracting officer must amend the solicitation to reflect the new NAICS code if ''the contracting officer receives OHA's decision by the date offers are due.'' Otherwise, OHA's decision does not apply to the pending procurement, but will apply only to future solicitations for the same supplies or services. If the solicitation is stayed, as required by § 121.1103(c)(1)(i), the contracting officer will always receive OHA's decision before the date offers are due. As such, this rule proposes to simply require that the contracting officer must amend the solicitation to reflect the new NAICS code whenever OHA changes a NAICS code in response to a NAICS code appeal. In addition, for clarity purposes, the proposed rule would revise § 121.1103(c)(1)(i) to provide that a contracting officer must stay the date of the closing of the receipt of offers instead of requiring that he or she must stay the solicitation. SBA is not revising these regulations to reflect a change in policy, but merely to more precisely capture what actually is being stayed.

III. Compliance With Executive Orders 12866, 12988, 13132, 13175, 13563, 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 proposed rule is a significant regulatory action for the purposes of Executive Order 12866. Accordingly, the next section contains SBA's Regulatory Impact Analysis. This is not a major rule, however, under the Congressional Review Act.

Regulatory Impact Analysis

1. *Is there a need for the regulatory action?*

In combining the 8(a) BD Mentor-Protégé Program and the All Small Mentor-Protégé Program, SBA seeks to eliminate confusion regarding perceived differences between the two Programs, remove unnecessary duplication of functions within SBA, and establish one, unified staff to better coordinate and process mentor-protégé applications. In addition, eliminating the requirement that SBA approve every joint venture in connection with an 8(a) contract will greatly reduce the time required for 8(a) BD Participants to come into and SBA to ensure compliance with SBA's joint venture requirements.

SBA is also proposing to make several changes to clarify its regulations. Through the years, SBA has spoken with small business and representatives and has determined that several regulations need further refinement so that they are easier to understand and implement. The proposed rule would

make several changes to ensure that the rules pertaining to SBA's various small business procurement programs are consistent. SBA believes that making the programs as consistent and similar as possible, where practicable, will make it easier for small businesses to understand what is expected of them and to comply with those requirements.

2. *What is the baseline, and the incremental benefits and costs of this regulatory action?*

The proposed regulations seek to address or clarify several issues, which will provide clarity to small businesses and contracting personnel. Further, SBA is proposing to eliminate the burden that 8(a) Participants seeking to be awarded an 8(a) contract as a joint venture must submit the joint venture to SBA for review and approval prior to contract award. There are currently approximately 4500 8(a) BD Participants in the portfolio. Of those, about 10% or roughly 450 Participants have entered a joint venture agreement to seek the award of an 8(a) contract. Under the current rules, SBA must approve the initial joint venture agreement itself and each addendum to the joint venture agreement—identifying the type of work and what percentage each partner to the joint venture would perform of a specific 8(a) procurement—prior to contract award. SBA reviews the terms of the joint venture agreement for regulatory compliance and must also assess the 8(a) BD Participant's capacity and whether the agreement is fair and equitable and will be of substantial benefit to the 8(a) concern. It is difficult to calculate the costs associated with submitting a joint venture agreement to SBA because the review process is highly fact-intensive and typically requires that 8(a) firms provide additional information and clarification. However, in the Agency's best professional judgment, it is estimated that an 8(a) Participant currently spends approximately three hours submitting a joint venture agreement to SBA and responding to questions regarding that submission. That equates to approximately 1,350 hours at an estimated rate of $44.06 per hour—the median wage plus benefits for accountants and auditors according to 2018 data from the Bureau of Labor Statistics—for an annual total cost savings to 8(a) Participants of about $59,500.

In addition, merging the 8(a) BD Mentor-Protégé Program into the All Small Mentor-Protégé Program would also provide cost savings. Firms seeking a mentor-protégé relationship through the All Small Mentor-Protégé Program apply through an on-line, electronic application system. 8(a) Participants seeking SBA's approval of a mentor-protégé relationship through the 8(a) BD program do not apply through an on-line, electronic system, but rather apply manually through their servicing SBA district office. In SBA's best professional judgment, the additional cost for submitting a manual mentor-protégé agreement to SBA for review and approval and responding manually to questions regarding that submission is estimated at two hours. SBA receives approximately 150 applications for 8(a) mentor-protégé relationships annually, which equates to an annual savings to prospective protégé firms of about 300 hours. At an estimated rate of $44.06 per hour, the annual savings in costs related to the reduced time for mentor-protégé applications through the All Small Mentor Protégé process is about $13,000 per year.

Moreover, eliminating the 8(a) BD Mentor-Protégé Program as a separate program and merging it with the All Small Mentor-Protégé Program will eliminate confusion firms seeking a mentor-protégé relationship have between the two programs. When SBA first implemented the All Small Mentor-Protégé Program, it intended to establish a program substantively identical to the 8(a) BD mentor-protégé program, as required by Section 1641 of the NDAA of 2013. Nevertheless, feedback from the small business community reveals a widespread misconception that the two programs offer different benefits. By merging the 8(a) BD Mentor-Protégé Program into the All Small-Mentor Protégé Program, firms will not have to read the requirements for both programs and try to decipher any perceived differences. SBA estimates that having one combined program will eliminate about one hour of preparation time for each firm seeking a mentor-protégé relationship. Based on approximately 600 mentor-protégé applications each year (about 450 for the All Small Mentor-Protégé Program and about 150 for the 8(a) BD Mentor-Protégé Program), this would equate to an annual cost savings to prospective protégé firms of about 600 hours. At an estimated rate of $44.06 per hour, the annual savings in costs related to the elimination of confusion caused by having two separate programs is about $26,500.

Thus, in total, the merger of the 8(a) BD mentor-protégé program into the All Small Business Mentor-Protégé Program would provide a cost savings of about $39,500 per year.

In addition, it generally takes between 60 and 90 days for SBA to approve a mentor-protégé relationship through the 8(a) BD program. Conversely, the average time it takes to approve a mentor-protégé relationship through the All Small Mentor-Protégé Program is about 20 working days. To firms seeking to submit offers through a joint venture with their mentors, this difference is significant. Such joint ventures are only eligible for the regulatory exclusion from affiliation if they are formed after SBA approves the underlying mentor-protégé relationship. It follows that firms applying through the 8(a) BD Mentor-Protégé Program could miss out on contract opportunities waiting for their mentor-protégé relationships to be approved. These contract opportunity costs are inherently difficult to measure, so SBA is requesting comments to better inform our understanding of the costs to the small business community. However, in SBA's best judgment, faster approval timeframes will mitigate such costs by giving program participants more certainty in planning their proposal strategies.

This rule also proposes to eliminate the requirement that any specific joint venture can be awarded no more than three contracts over a two year period, but would instead permit a joint venture to be awarded an unlimited number of contracts over a two year period. The change removing the limit of three awards to any joint venture would reduce the burden of small businesses being required to form additional joint venture entities to perform a fourth contract within that two-year period. SBA has observed that joint ventures are often established as separate legal entities—specifically as limited liability corporations—based on considerations related to individual venture liability, tax liability, regulatory requirements, and exit strategies. Under the current rule joint venture partners must form a new joint venture entity after receiving three contracts lest they be deemed affiliated for all purposes. The proposed rule which allows a joint venture to continue to seek and be awarded contracts without requiring the partners to form a new joint venture entity after receiving its third contract would save small businesses significant legal costs in establishing new joint ventures and ensuring that those entities meet all applicable regulatory requirements.

The proposed rule would also make several changes to reduce the burden of recertifying small business status generally and requesting changes of ownership in the 8(a) BD program. Specifically, the proposed rule would clarify that a concern that is at least 51% owned by an entity (*i.e.,* tribe, ANC, or Community Development Corporation (CDC)) need not recertify its

status as a small business when the ownership of the concern changes to or from a wholly-owned business concern of the same entity, as long as the ultimate owner remains that entity. In addition, the proposed rule would also provide that a Participant in SBA's 8(a) BD program that is owned by an ANC or tribe need not request a change of ownership from SBA where the ANC or tribe merely reorganizes its ownership of a Participant in the 8(a) BD program by inserting or removing a wholly-owned business entity between the ANC/tribe and the Participant. Both of these changes would save entity-owned small business concerns a significant amount of time and money. Similarly, the proposed rule would provide that prior SBA approval is not needed where the disadvantaged individual (or entity) in control of a Participant in the 8(a) BD program will increase the percentage of his or her (its) ownership interest.

The proposed rule would also allow a concern that has been declined for 8(a) BD program participation to submit a new application 90 days after the date of the Agency's final decision to decline. This would change the current rule which requires a concern to wait 12 months from the date of the final agency decision to reapply. This would allow firms that have been declined from participating in the 8(a) BD program the opportunity to correct deficiencies, come into compliance with program eligibility requirements, reapply and be admitted to the program and receive the benefits of the program much more quickly. SBA understands that by reducing the re-application waiting period there is the potential to strain the agency's resources with higher application volumes. Because these potential costs are difficult to quantify, SBA is seeking comments to further examine this proposal. However, in the Agency's best judgment, any costs associated with the increase in application volume would be outweighed by the potential benefit of providing business development assistance and contracting benefits sooner to eligible firms.

This rule also proposes to clarify SBA's position with respect to size and socioeconomic status certifications on task orders under MACs. Currently, size certifications at the order level are not required unless the contracting officer, in his or her discretion, requests a recertification in connection with a specific order. The proposed rule would require a concern to submit a recertification or confirm its size and/or socioeconomic status for all set-aside orders (*i.e.,* small business set-aside, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business) under unrestricted MACs, except for orders or Blanket Purchase Agreements issued under any FSS contracts. Additionally, the proposed rule would require a concern to submit a recertification or confirm its socioeconomic status for all set-aside orders where the required socioeconomic status for the order differs from that of the underlying set aside MAC. If the firm's size and status in SAM is current and accurate when the firm submits its offer, the concern would not need to submit a new certification or submit any additional documentation with its offer. SBA recognizes that confirming accurate size and socioeconomic status imposes a burden on a small business contract holder, but the burden is minimal. SBA intends that confirmation of size and status under this rule would be satisfied by confirming that the firm's size and status in SAM is currently accurate and qualifies the firm for award.

FPDS–NG indicates that, in Fiscal Year 2018, agencies set aside about 1,400 orders per year off unrestricted MACs, excluding orders under FSS contracts. SBA adopts the assumption from FAR Case 2014–002 that on average there are three offers per set-aside order. The annual cost of requiring present size and socioeconomic status on set-aside orders under unrestricted MACs, excluding FSS orders, therefore is calculated as 1,400 orders × 3 offers per order × 15 minutes per offer × $44.06 cost per hour. This amounts to an annual public burden of about $46,250.

FPDS–NG indicates that, in Fiscal Year 2018, agencies set aside about 400 orders per year off set-aside MACs, other than the FSS, in the categories covered by this rule. These categories are WOSB or EDWOSB set-aside/sole-source orders off small business set-aside MACs; SDVOSB set-aside/sole-source orders off small business set-aside MACs; WOSB or EDWOSB set-aside/sole-source orders off any small business program MAC (8(a), HUBZone, WOSB/EDWOSB, and SDVOSB); and SDVOSB set-aside/sole-source order off 8 any small business program MAC (8(a), HUBZone, WOSB/EDWOSB, and SDVOSB). Following the same calculations, the annual cost of requiring present socioeconomic status on set-aside orders under set-aside MACs, is calculated as 400 orders × 3 offers per order × 15 minutes per offer × $44.06 cost per hour. This amounts to an annual public burden of about $13,200.

As reflected in the calculation, SBA believes that being presently qualified for the required size or socioeconomic status on an order, where required, would impose a burden on small businesses. A concern already is required by law to update its size and status certifications in SAM at least annually. As such, the added burden to industry is limited to confirming that the firm's certification is current and accurate.

The added burden to ordering agencies includes the act of checking a firm's size and status certification in SAM at the time of order award. Since ordering agencies are already familiar with checking SAM information, such as to ensure that an order awardee is not debarred, suspended, or proposed for debarment, this verification is de minimis. Further, checking SAM at time of order award replaces the check of the offeror's contract level certification. SBA recognizes, however, that an agency's market research for the order level may be impacted where the agency intends to issue a set-aside order off an unrestricted vehicle (or a socioeconomic set-aside off a small business set-aside vehicle). The ordering agency may need to identify MAC-eligible vendors and then find their status in SAM. This is particularly the case where the agency is applying the Rule of Two and verifying that there are at least two small businesses or small businesses with the required status sufficient to set aside the order. SBA does not believe that conducting SAM research is onerous; however, because this rule does not cover the FSS and does not cover orders set aside within the same category as the contract, agencies have readily available alternatives to avoid using SAM.

Using the same set-aside order data, the annual cost of additional market research efforts for applicable set-aside orders under MACs, is calculated as 2,400 orders (1,400 + 1,000) × 10 minutes per order × $44.06 cost per hour. This amounts to an annual government burden of about $17,600.

The annual cost is partially offset by the cost savings that result from other changes in this rule. This proposed change goes more to accountability and ensuring that small business contracting vehicles truly benefit small business concerns. Nevertheless, SBA is requesting comments to further assess potential incremental costs.

3. *What are the alternatives to this proposed rule?*

As noted above, this rule proposes to make a number of changes intended to reduce unnecessary or excessive burdens on small businesses, and to

clarify other regulatory provisions to eliminate confusion among small businesses and procuring activities. SBA has also considered other alternative proposals to achieve these ends. Concerning SBA's role in approving 8(a) joint venture agreements, the Agency could also eliminate the requirement that SBA must approve joint ventures in connection with sole source 8(a) awards. However, as noted above, SBA believes that such approval is an important enforcement mechanism to ensure that the joint venture rules are followed. With respect to the requirement that a concern must wait 90 days to re-apply to the 8(a) BD program after the date of the Agency's final decline decision, SBA could instead eliminate the application waiting period altogether. This would allow a concern to re-apply as soon as it reasonably believed it had overcome the grounds for decline. However, SBA believes that such an alternative would encompass significant administrative burden on SBA.

Under the proposed rule, if an order under an unrestricted MAC is set-aside exclusively for small business (*i.e.,* small business set-aside, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), or the order is set aside in a different category than was the set-aside MAC, a concern must be qualified for the required size and socioeconomic status at the time it submits its initial offer, which includes price, for the particular order. In SBA's view, the order is the first time size or socioeconomic status is important where the underlying MAC is unrestricted or set aside in a different category than the set-aside MAC, and therefore, that is the date at which eligibility should be examined. SBA considered maintaining the status quo; allowing a one-time certification as to size and socioeconomic status (*i.e.,* at the time of the initial offer for the underlying contract) to control all orders under the contract, unless one of recertification requirements applies (see 121.404(g)). SBA believes the current policy does not properly promote the interests of small business. Long-term contracting vehicles that reward firms that once were, but no longer qualify as, small or a particular socioeconomic status adversely affect truly small or otherwise eligible businesses.

Another alternative is to require business concerns to notify contracting agencies when there is a change to a concern's socioeconomic status (*e.g.,* HUBZone, WOSB, etc.), such that they would no longer qualify for set-aside orders. The contracting agency would then be required to issue a contract modification within 30 days, and from that point forward, ordering agencies would no longer be able to count options or orders issued pursuant to the contract for small business goaling purposes. This could be less burdensome than recertification of socioeconomic status for each set-aside order. SBA invites comments on consideration of this approach.

Summary of Costs and Cost Savings

Table 1: Summary of Incremental Costs and Cost Savings, below, sets out the estimated net incremental cost/(cost saving) associated with this proposed rule. Table 2: Detailed Breakdown of Incremental Costs and Cost Savings, below, provides a detailed explanation of the annual cost/(cost saving) estimates associated with this proposed rule. This proposed rule is expected to be an E.O. 13771 deregulatory action. The annualized cost savings of this rule is expected to be $21,065 in 2016 dollars with a net present value of $300,935 over perpetuity.

TABLE 1—SUMMARY OF INCREMENTAL COSTS AND COST SAVINGS

Item No.	Regulatory action item	Annual cost/ (cost saving) estimate
1	Eliminating SBA approval of joint venture agreements to perform competitive 8(a) contracts	($59,500)
2	Merging the 8(a) BD Mentor-Protégé Program into the All Small Mentor-Protégé Program—Elimination of manual application process.	(13,000)
3	Merging the 8(a) BD Mentor-Protégé Program into the All Small Mentor-Protégé Program—Elimination of confusion among firms seeking a mentor-protégé relationship.	(26,500)
4	Requiring recertification for set-aside orders issued off unrestricted Multiple Award Contracts	46,250
5	Requiring recertification for set-aside orders issued off set-aside Multiple Award Contracts	13,200
6	Additional Government detailed market research to identify qualified sources for set-aside orders	17,600

TABLE 2—DETAILED BREAKDOWN OF INCREMENTAL COSTS AND COST SAVINGS

Item No.	Regulatory action item details	Annual cost/ (cost saving) estimate breakdown
1	*Proposed regulatory change:* SBA is proposing to eliminate the burden that 8(a) Participants seeking to be awarded an 8(a) contract as a joint venture must submit the joint venture to SBA for review and approval prior to contract award.	
	Estimated number of impacted entities: There are currently approximately 4500 8(a) BD Participants in the portfolio. Of those, about 10% or roughly 450 Participants have entered a joint venture agreement to seek the award of an 8(a) contract.	450 entities.
	Estimated average impact (labor hour):* SBA estimates that an 8(a) BD Participant currently spends approximately three hours submitting a joint venture agreement to SBA and responding to questions regarding that submission.	3 hours
	*2017 Median Pay** (per hour):* Most 8(a) firms use an accountant or someone with similar skills for this task	$44.06.
	Estimated Cost/(Cost Saving)	($59,500)
2	*Proposed regulatory change:* SBA is proposing to merge the 8(a) BD Mentor-Protégé Program into the All Small Mentor-Protégé Program. This will reduce the burden on 8(a) Participants seeking a mentor-protégé.	
	Estimated number of impacted entities: SBA receives approximately 150 applications for 8(a) mentor-protégé relationships annually.	150 entities.

TABLE 2—DETAILED BREAKDOWN OF INCREMENTAL COSTS AND COST SAVINGS—Continued

Item No.	Regulatory action item details	Annual cost/ (cost saving) estimate breakdown
	Estimated average impact (labor hour):* In SBA's best professional judgment, the additional cost for submitting a manual mentor-protégé agreement to SBA for review and approval and responding manually to questions regarding that submission is estimated at two hours.	2 hours.
	*2017 Median Pay** (per hour):* Most 8(a) firms use an accountant or someone with similar skills for this task	$44.06.
	Estimated Cost/(Cost Saving)	($13,000)
3	*Proposed regulatory change:* SBA is proposing to merge the 8(a) BD Mentor-Protégé Program into the All Small Mentor-Protégé Program. In doing so, firms will not have to read the requirements for both programs and try to decipher any perceived differences..	
	Estimated number of impacted entities: SBA receives approximately 600 mentor-protégé applications each year—about 450 for the All Small Mentor-Protégé Program and about 150 for the 8(a) BD Mentor-Protégé Program).	600 entities.
	Estimated average impact (labor hour):* SBA estimates that having one combined program will eliminate about one hour of preparation time for each firm seeking a mentor-protégé relationship.	1 hour.
	*2017 Median Pay** (per hour):* Most small business concerns use an accountant or someone with similar skills for this task.	$44.06.
	Estimated Cost/(Cost Saving)	($26,500)
4	*Proposed regulatory change:* SBA is proposing to require that a firm be accurately certified and presently qualified as to size and/or status for set-aside orders issued off Multiple Award Contracts that were not set aside or set aside in a separate category, except for the Federal Supply Schedule.	
	Estimated number of impacted entities: Approximately 1,400 set-aside orders are issued annually on Multiple Award Contracts that are not set aside in the same category, other than on the Federal Supply Schedule. SBA estimates that three offers are submitted for each order.	4,200 offers.
	Estimated average impact (labor hour):* SBA estimates that a small business will spend an average of 15 minutes confirming that size and status is accurate prior to submitting an offer.	0.25 hours.
	*2017 Median Pay** (per hour):* Most small business concerns use an accountant or someone with similar skills for this task.	$44.06
	Estimated Cost/(Cost Saving)	$46,250.
5	*Proposed regulatory change:* SBA is proposing to require that a firm be accurately certified and presently qualified as to socioeconomic status for set-aside orders issued off Multiple Award Contracts that were set aside in a separate category, except for the Federal Supply Schedule contracts.	
	Estimated number of impacted entities: Approximately 400 set-aside orders are issued annually on Multiple Award Contracts that are not set aside in the same category, other than on the Federal Supply Schedule, are affected by this rule. SBA estimates that three offers are submitted for each order.	1,200 offers.
	Estimated average impact (labor hour):* SBA estimates that a small business will spend an average of 15 minutes confirming that size and status is accurate prior to submitting an offer.	0.25 hours.
	*2017 Median Pay** (per hour):* Most small business concerns use an accountant or someone with similar skills for this task.	$44.06.
	Estimated Cost/(Cost Saving)	$13,200.
6	*Proposed regulatory change:* SBA is proposing to require that firms be accurately certified and presently qualified as to size and socioeconomic status for certain set-aside orders issued off Multiple Award Contracts, except for the Federal Supply Schedule contracts. This change impacts the market research required by ordering activities to determine if a set-aside order for small business or for any of the socioeconomic programs may be pursued.	
	Estimated number of impacted entities: Approximately 2,400 set-aside orders are issued annually as described in the proposed rule on Multiple Award Contracts, other than on the Federal Supply Schedule. 33000.	2,400 orders.
	Estimated average impact (labor hour):* SBA estimates that ordering activities applying the Rule of Two will spend an average of 10 additional minutes to locate contractors awarded MACs and looking up the current business size for each of the contractors in SAM to determine if a set-aside order can be pursued.	0.16 hours.
	*2017 Median Pay** (per hour):* Contracting officers typically perform the market research for the acquisition plan.	$44.06.
	Estimated Cost/(Cost Saving)	$17,600.

* This estimate is based on SBA's best professional judgment.
** Source: Bureau of Labor Statistics, Accountants and Auditors.

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. The action does not have retroactive or preemptive effect.

Executive Order 13132

For the purposes of Executive Order 13132, SBA has determined that this proposed 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, for the purpose of Executive Order 13132, Federalism, SBA has determined that this proposed rule has no federalism implications warranting preparation of a federalism assessment.

Executive Order 13175

As part of this proposed rulemaking process SBA held tribal consultations pursuant to Executive Order 13175, Tribal Consultations, in Anchorage, AK

(*see* 83 FR 17626), Albuquerque, NM (*see* 83 FR 24684), and Oklahoma City, OK (*see* 83 FR 24684). This executive order reaffirms the Federal Government's commitment to tribal sovereignty and requires Federal agencies to consult with Indian tribal governments when developing policies that would impact the tribal community. The purpose of the above-referenced tribal consultation meetings was to provide interested parties with an opportunity to discuss their views on the issues, and for SBA to obtain the views of SBA's stakeholders on approaches to the 8(a) BD program regulations. SBA has always considered tribal consultation meetings a valuable component of its deliberations and believes that these tribal consultation meetings allow for constructive dialogue with the Tribal community, Tribal Leaders, Tribal Elders, elected members of Alaska Native Villages or their appointed representatives, and principals of tribally-owned and ANC-owned firms participating in the 8(a) BD program.

In general, tribal stakeholders were supportive of SBA's intent to implement changes that will make it easier for small business concerns to understand and comply with the regulations governing the 8(a) BD program, and agreed that this rulemaking will make the program more effective and accessible to the small business community. SBA received significant comments on its approaches to the proposed regulatory changes, as well as several recommendations regarding the 8(a) BD program not initially contemplated by this planned rulemaking. SBA has taken these discussions into account in drafting this proposed rule. SBA intends to hold additional tribal consultations before issuing a final rule.

Executive Order 13563

This executive order directs agencies to, among other things: (a) Afford the public a meaningful opportunity to comment through the internet on proposed regulations, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among government officials, experts, stakeholders, and the public; and (c) seek the views of those who are likely to be affected by the rulemaking, even before issuing a notice of proposed rulemaking. As far as practicable or relevant, SBA considered these requirements in developing this rule, as discussed below.

1. *Did the agency use the best available techniques to quantify anticipated present and future costs when responding to E.O. 12866 (e.g., identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes)?*

To the extent possible, the agency utilized the most recent data available in the Federal Procurement Data System—Next Generation (FPDS–NG), Dynamic Small Business Search (DSBS) and System for Award Management (SAM).

2. *Public participation: Did the agency: (a) Afford the public a meaningful opportunity to comment through the internet on any proposed regulation, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among government officials, experts, stakeholders, and the public; (c) provide timely online access to the rulemaking docket on Regulations.gov; and (d) seek the views of those who are likely to be affected by rulemaking, even before issuing a notice of proposed rulemaking?*

The proposed rule will have a 60-day comment period and will be posted on *www.regulations.gov* to allow the public to comment meaningfully on its provisions. In addition, SBA submitted the proposed rule to the Office of Management and Budget for interagency review.

3. *Flexibility: Did the agency identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public?*

Yes, the proposed rule is intended to reduce unnecessary or excessive burdens on 8(a) Participants, and clarify other regulatory related provisions to eliminate confusion among small businesses and procuring activities.

Executive Order 13771

This proposed rule is expected to be an E.O. 13771 deregulatory action. The annualized cost savings of this rule is expected to be $21,065 in 2016 dollars with a net present value of $300,935 over perpetuity. A detailed discussion of the estimated cost of this proposed rule can be found in the above Regulatory Impact Analysis.

Paperwork Reduction Act, 44 U.S.C. Ch. 35

This proposed rule does impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C. Chapter 35. The rule provides a number of size and/or socioeconomic status recertification requirements for set-aside orders under MACs. The annual total public reporting burden for this collection of information is estimated to be 1,800 total hours ($79,300), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing information reporting.

Respondents: 7,200.
Responses per respondent: 1.
Total annual responses: 7,200.
Preparation hours per response: 0.25 (15 min).
Total response burden hours: 1,800.
Cost per hour: $44.06.
Estimated cost burden to the public: $79,300.

This added information collection burden will be officially reflected through OMB Control Number 9000–0163 if the rule is implemented.

SBA invites comments, particularly on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA) requires administrative agencies to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. Pursuant to the RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis which describes the impact of the rule on small entities. However, section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. The RFA defines ''small entity'' to include ''small businesses,'' ''small organizations,'' and ''small governmental jurisdictions.''

This proposed rule concerns various aspects of SBA's 8(a) BD program, as such the rule relates to small business concerns but would not affect ''small organizations'' or ''small governmental jurisdictions'' because those programs generally apply only to ''business concerns'' as defined by SBA regulations, in other words, to small businesses organized for profit. ''Small organizations'' or ''small governmental

jurisdictions'' are non-profits or governmental entities and do not generally qualify as ''business concerns'' within the meaning of SBA's regulations.

There are currently approximately 4500 8(a) BD Participants in the portfolio. Most of the proposed changes are clarification of current policy or designed to reduce unnecessary or excessive burdens on 8(a) BD Participants and therefore should not impact many of these concerns. There are about 385 Participants with 8(a) BD mentor-protégé agreements and about another 850 small businesses that have SBA-approved mentor-protégé agreements through the All Small Mentor-Protégé Program. The consolidation of SBA's two mentor-protégé programs into one program will not have a significant economic impact on small businesses. In fact, it should have no affect at all on those small businesses that currently have or on those that seek to have an SBA-approved mentor-protégé relationship. The proposed rule would eliminate confusion regarding perceived differences between the two Programs, remove unnecessary duplication of functions within SBA, and establish one, unified staff to better coordinate and process mentor-protégé applications. The benefits of the two programs are identical, and will not change under the proposed rule.

SBA is also proposing to require a business to be qualified for the required size and status when under consideration for a set-aside order off a MAC that was awarded outside of the same set-aside category. Pursuant to the Small Business Goaling Report (SBGR) Federal Procurement Data System—Next Generation (FPDS–NG) records, about 236,000 new orders were awarded off MACs per year from FY 2014 to FY 2018. Around 199,000, or 84.3 percent, were awarded off MACs established without a small business set aside. For this analysis, small business set asides include all total or partial small business set asides; and all 8(a), WOSB, SDVOSB, and HUBZone awards. There were about 9,000 new orders awarded annually with a small business set aside off MACs established without a small business set aside. These orders were issued to approximately 2,600 firms. The 9,000 new orders awarded with a small business set aside off a MAC without a small business set aside were 4.0 percent of the 236,000 new orders off MACs in a year (Table 3). In FY 2018, only 1,400 for these set-aside orders used MACs other than the FSS Program.

TABLE 3—0.47% OF NEW MAC ORDERS IN A FY ARE NON-FSS ORDERS SET ASIDE FOR SMALL BUSINESS WHERE UNDERLYING BASE CONTRACT NOT SET ASIDE FOR SMALL BUSINESS

	FY 014	FY 015	FY 016	FY 017	FY 018	AVG
Total new modification 0 orders off MACs in FY	244,664	231,694	245,978	234,304	223,861	236,100
Orders awarded with SB set aside without MAC IDV SB set aside	10,089	9,347	9,729	9,198	8,666	9,406
Non-FSS orders awarded with SB set aside without MAC IDV SB set aside	902	780	1,019	1,422	1,400	1,105
Percent	0.37%	0.34%	0.41%	0.61%	0.63%	0.47%

If all firms receiving a non-FSS small business set aside order off a MAC that was not itself set aside for small business were adversely affected by the proposed rule (*i.e.,* every such firm receiving an award as a small business had grown to be other than a small business or no longer qualified as 8(a), WOSB, SDVO, or HUBZone), the rule requiring a business to be certified as small for a non-FSS small business set aside orders off MACs not set aside for small business would impact only 0.47 percent of annual new MAC orders. As such, SBA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, throughout the supplementary information to this proposed rule, SBA has identified the reasons why the proposed changes are being considered, the objectives and basis for the proposed rule, a description of the number of small entities to which the proposed rule will apply, and a description of alternatives considered.

List of Subjects

13 CFR Part 121

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

13 CFR Part 124

Administrative practice and procedure, Government procurement, Government property, Small businesses.

13 CFR Part 125

Government contracts, Government procurement, Reporting and recordkeeping requirements, Small businesses, Technical assistance.

13 CFR Part 126

Administrative practice and procedure, Government procurement, Penalties, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 127

Government contracts, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 134

Administrative practice and procedure, Claims, Equal employment opportunity, Lawyers, Organization and functions (Government agencies).

Accordingly, for the reasons stated in the preamble, SBA proposes to amend 13 CFR parts 121, 124, 125, 126, 127, and 134 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. Amend § 121.103 by:
■ a. Revising the first sentence of paragraphs (b)(6) and (9);
■ b. Revising paragraph (f)(2)(i);
■ c. Revising the first sentence of paragraph (g);
■ d. Revising paragraph (h) introductory text and example 1 to paragraph (h) introductory text;
■ e. Adding two sentences to the end of paragraph (h)(3)(ii);
■ f. Removing paragraph (h)(3)(iii); and
■ g. Revising paragraph (h)(5).

The revisions and addition read as follows:

§ 121.103 How does SBA determine affiliation?

* * * * *

(b) * * *

(6) A firm that has an SBA-approved mentor-protégé agreement authorized under § 125.9 of this chapter is not affiliated with its mentor or protégé firm solely because the protégé firm receives assistance from the mentor under the agreement. * * *

* * * * *

(9) In the case of a solicitation for a bundled contract or a Multiple Award Contract with a value in excess of the agency's substantial bundling threshold, a small business contractor may enter into a Small Business Teaming Arrangement with one or more small business subcontractors and submit an offer as a small business without regard to affiliation, so long as each team member is small for the size standard assigned to the contract or subcontract. * * *

* * * * *

(f) * * *

(2) * * *

(i) This presumption may be rebutted by a showing that despite the contractual relations with another concern, the concern at issue is not solely dependent on that other concern, such as where the concern has been in business for a short amount of time and has only been able to secure a limited number of contracts or where the contractual relations do not restrict the concern in question from selling the same type of products or services to another purchaser.

* * * * *

(g) *Affiliation based on the newly organized concern rule.* Affiliation may arise where former or current officers, directors, principal stockholders, managing members, or key employees of one concern organize a new concern in the same or related industry or field of operation, and serve as the new concern's officers, directors, principal stockholders, managing members, or key employees, and the one concern is furnishing or will furnish the new concern with contracts, financial or technical assistance, indemnification on bid or performance bonds, and/or other facilities, whether for a fee or otherwise. * * *

(h) *Affiliation based on joint ventures.* A joint venture is an association of individuals and/or concerns with interests in any degree or proportion consorting to engage in and carry out business ventures for joint profit over a two year period, for which purpose they combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally. This means that a specific joint venture entity generally may not be awarded contracts beyond a two-year period, starting from the date of the award of the first contract, without the partners to the joint venture being deemed affiliated for the joint venture. Once a joint venture receives a contract, it may submit additional offers for a period of two years from the date of that first award. An individual joint venture may be awarded one or more contracts after that two-year period as long as it submitted an offer including price prior to the end of that two-year period. SBA will find joint venture partners to be affiliated, and thus will aggregate their receipts and/or employees in determining the size of the joint venture for all small business programs, where the joint venture submits an offer after two years from the date of the first award. The same two (or more) entities may create additional joint ventures, and each new joint venture entity may submit offers for a period of two years from the date of the first contract to the joint venture without the partners to the joint venture being deemed affiliates. At some point, however, such a longstanding inter-relationship or contractual dependence between the same joint venture partners will lead to a finding of general affiliation between and among them. A joint venture: Must be in writing; must do business under its own name and be identified as a joint venture in the System for Award Management (SAM) for the award of a prime contract; may be in the form of a formal or informal partnership or exist as a separate limited liability company or other separate legal entity; and, if it exists as a formal separate legal entity, may not be populated with individuals intended to perform contracts awarded to the joint venture (*i.e.,* the joint venture may have its own separate employees to perform administrative functions, including one or more Facility Security Officer(s), but may not have its own separate employees to perform contracts awarded to the joint venture). SBA may also determine that the relationship between a prime contractor and its subcontractor is a joint venture pursuant to paragraph (h)(4) of this section. For purposes of this paragraph (h), contract refers to prime contracts, novations of prime contracts, and any subcontract in which the joint venture is treated as a similarly situated entity as the term is defined in part 125 of this chapter.

Example 1 to paragraph (h) introductory text. Joint Venture AB receives a contract on April 2, year 1. Joint Venture AB may receive additional contracts through April 2, year 3. On June 6, year 2, Joint Venture AB submits an offer for Solicitation 1. On July 13, year 2, Joint Venture AB submits an offer for Solicitation 2. In May, year 3, Joint Venture AB is found to be the apparent successful offeror for Solicitation 1. In June, year 3, Joint Venture AB is found to be the apparent successful offeror for Solicitation 2. Even though the award of the two contracts emanating from Solicitations 1 and 2 would occur after April 2, year 3, Joint Venture AB may receive those awards without causing general affiliation between its joint venture partners because the offers occurred prior to the expiration of the two-year period.

* * * * *

(3) * * *

(ii) * * * Except for sole source 8(a) awards, the joint venture must meet the requirements of § 124.513(c) and (d), § 125.8(b) and (c), § 125.18(b)(2) and (3), § 126.616(c) and (d), or § 127.506(c) and (d) of this chapter, as appropriate, at the time it submits its initial offer including price. For a sole source 8(a) award, the joint venture must demonstrate that it meets the requirements of § 124.513(c) and (d) prior to the award of the contract.

* * * * *

(5) For size purposes, a concern must include in its receipts its proportionate share of joint venture receipts, unless the proportionate share already is accounted for in receipts reflecting transactions between the concern and its joint ventures (*e.g.,* subcontracts from a joint venture entity to joint venture partners). In determining the number of employees, a concern must include in its total number of employees its proportionate share of joint venture employees. For both the calculation of receipts and of employees, the appropriate proportionate share is the same percentage of receipts or employees as the joint venture partner's percentage share of the work performed by the joint venture.

Example 1 to paragraph (h)(5). Joint Venture AB is awarded a contract for $10M. The joint venture will perform 50% of the work, with A performing $2M (40% of the 50%, or 20% of the total value of the contract) and B performing $3M (60% of the 50% or 30% of the total value of the contract). Since A will perform 40% of the work done by the joint venture, its share of the revenues for the entire contract is 40%, which means that the receipts from the contract awarded to Joint Venture AB that must be included in A's receipts for size purposes are $4M. A must add $4M to its receipts for size purposes, unless its receipts

already account for the $4M in transactions between A and Joint Venture AB.

* * * * *

■ 3. Amend § 121.402 by:
■ a. Revising the first sentence of paragraph (b)(2);
■ b. Revising paragraph (c)(1)(i);
■ c. Redesignating paragraph (c)(2)(ii) as paragraph (c)(2)(iii); and
■ d. Adding a new paragraph (c)(2)(ii).

The revisions and addition read as follows:

§ 121.402 What size standards are applicable to Federal Government Contracting programs?

* * * * *

(b) * * *

(2) A procurement is generally classified according to the component which accounts for the greatest percentage of contract value. * * *

(c) * * *

(1) * * *

(i) Assign the solicitation a single NAICS code and corresponding size standard which best describes the principal purpose of the acquisition as set forth in paragraph (b) of this section, only if the NAICS code will also best describe the principal purpose of each order to be placed under the Multiple Award Contract; or

* * * * *

(2) * * *

(ii) The contracting officer must assign a single NAICS code for each order issued against a Multiple Award Contract. The NAICS code assigned to an order must be a NAICS code included in the underlying Multiple Award Contract. When placing an order under a Multiple Award Contract with multiple NAICS codes, the contracting officer must assign the NAICS code and corresponding size standard that best describes the principal purpose of each order. In cases like the GSA Schedule, where an agency can issue an order against multiple SINs with different NAICS codes, the contracting officer must select the single NAICS code that best represents the acquisition. If the base contract has not been assigned a NAICS code that reflects the principal purpose of the order, the contracting officer shall select a new NAICS code and corresponding size standard for the order.

* * * * *

■ 4. In § 121.404:
■ a. Amend paragraph (a) by:
■ i. Revising paragraphs (a) introductory text and (a)(1); and
■ ii. Adding a subject heading to paragraph (a)(2);
■ b. Revise paragraph (b);
■ c. Add a subject heading to paragraph (c);
■ d. Revise paragraph (d);
■ e. Add a subject heading to paragraph (e) and a sentence at the end of paragraph (e);
■ f. Add a subject heading to paragraph (f);
■ g. Amend paragraph (g) by:
■ i. Revising paragraph (g) introductory text and paragraphs (g)(2)(ii)(C) and (D);
■ ii. Adding paragraph (g)(2)(iii) and a new second sentence to paragraph (g)(3) introductory text; and
■ h. Add a subject heading to paragraph (h).

The additions and revisions read as follows:

§ 121.404 When is the size status of a business concern determined?

(a) *Time of size*—(1) *Multiple award contracts.* With respect to Multiple Award Contracts, orders issued against a Multiple Award Contract, and Blanket Purchase Agreements issued against a Multiple Award Contract:

(i) *Single NAICS.* If a single NAICS code is assigned as set forth in § 121.402(c)(1)(i), SBA determines size status for the underlying Multiple Award Contract at the time of initial offer (or other formal response to a solicitation), which includes price, based upon the size standard set forth in the solicitation for the Multiple Award Contract, unless the concern was required to recertify under paragraph (g)(1), (2), or (3).

(A) *Unrestricted Multiple Award Contracts.* For an unrestricted Multiple Award Contract, if a business concern is small at the time of offer and contract-level recertification for the Multiple Award Contract, it is small for goaling purposes for each order issued against the contract, unless a contracting officer requests a size recertification for a specific order or Blanket Purchase Agreement. However, except for orders and Blanket Purchase Agreements issued under any Federal Supply Schedule contract, if an order or a Blanket Purchase Agreement under an unrestricted Multiple Award Contract is set-aside exclusively for small business (*i.e.,* small business set-aside, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), a concern must recertify its size status and qualify as a small business at the time it submits its initial offer, which includes price, for the particular order or Blanket Purchase Agreement.

(B) *Set-aside Multiple Award Contracts.* For a Multiple Award Contract that is set aside for small business (*i.e.,* small business set, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), if a business concern is small at the time of offer and contract-level recertification for the Multiple Award Contract, it is small for each order or Blanket Purchase Agreement issued against the contract, unless a contracting officer requests a size recertification for a specific order or Blanket Purchase Agreement.

(ii) *Multiple NAICS.* If multiple NAICS codes are assigned as set forth in § 121.402(c)(1)(ii), SBA determines size status at the time of initial offer (or other formal response to a solicitation), which includes price, for a Multiple Award Contract based upon the size standard set forth for each discrete category (*e.g.,* CLIN, SIN, Sector, FA or equivalent) for which a business concern submits an offer and represents it is small for the Multiple Award Contract, unless the firm was required to recertify under paragraph (g)(1), (2), or (3). If the business concern submits an offer for the entire Multiple Award Contract, SBA will determine whether it meets the size standard for each discrete category (CLIN, SIN, Sector, FA or equivalent).

(A) *Unrestricted Multiple Award Contracts.* For an unrestricted Multiple Award Contract, if a business concern is small at the time of offer and contract-level recertification for discrete categories on the Multiple Award Contract, it is small for goaling purposes for each order issued against any of those categories, unless a contracting officer requests a size recertification for a specific order or Blanket Purchase Agreement. However, except for orders or Blanket Purchase Agreements issued under any Federal Supply Schedule contract, if an order or Blanket Purchase Agreement for a discrete category under an unrestricted Multiple Award Contract is set-aside exclusively for small business (*i.e.,* small business set, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), a concern must recertify its size status and qualify as a small business at the time it submits its initial offer, which includes price, for the particular order or Agreement.

(B) *Set-aside Multiple Award Contracts.* For a Multiple Award Contract that is set aside for small business (*i.e.,* small business set, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business), if a business is small at the time of offer and contract-level recertification for discrete categories on the Multiple Award

Contract, it is small for each order or Agreement issued against any of those categories, unless a contracting officer requests a size recertification for a specific order or Blanket Purchase.

(iii) SBA will determine size at the time of initial offer (or other formal response to a solicitation), which includes price, for an order or Agreement issued against a Multiple Award Contract if the contracting officer requests a new size certification for the order or Agreement.

(2) *Agreements.* * * *

(b) *Eligibility for SBA programs.* A concern applying to be certified as a Participant in SBA's 8(a) Business Development program (under part 124, subpart A, of this chapter), as a HUBZone small business (under part 126 of this chapter), or as a women-owned small business concern (under part 127 of this chapter) must qualify as a small business for its primary industry classification as of the date of its application and, where applicable, the date the SBA program office requests a formal size determination in connection with a concern that otherwise appears eligible for program certification.

(c) *Certificates of competency.* * * *

(d) *Nonmanufacturer rule, ostensible subcontractor rule, and joint venture agreements.* Size status is determined as of the date of the final proposal revision for negotiated acquisitions and final bid for sealed bidding for the following purposes: compliance with the nonmanufacturer rule set forth in § 121.406(b)(1), the ostensible subcontractor rule set forth in § 121.103(h)(4), and the joint venture agreement requirements in § 124.513(c) and (d), § 125.8(b) and (c), § 125.18(b)(2) and (3), § 126.616(c) and (d), or § 127.506(c) and (d) of this chapter, as appropriate.

(e) *Subcontracting.* * * * A prime contractor may rely on the self-certification of subcontractor provided it does not have a reason to doubt the concern's self-certification.

(f) *Two-step procurements.* * * *

(g) *Effect of size certification and recertification.* A concern that represents itself as a small business and qualifies as small at the time of its initial offer (or other formal response to a solicitation), which includes price, and after a required recertification under paragraph (g)(1), (2), or (3) of this section is generally considered to be a small business throughout the life of that contract. Where a concern grows to be other than small, the procuring agency may exercise options and still count the award as an award to a small business, except that a required recertification as other than small under paragraph (g)(1), (2), or (3) of this section changes the firm's status for future options and orders. The following exceptions apply to this paragraph (g):

* * * * *

(2) * * *

(ii) * * *

(C) In the context of a joint venture that has been awarded a contract or order as a small business, from any partner to the joint venture that has been acquired, is acquiring, or has merged with another business entity.

(D) If the merger, sale or acquisition occurs after offer but prior to award, the offeror must recertify its size to the contracting officer prior to award. If the offeror is unable to recertify as small, it will not be eligible as a small business for the award of the contract.

(iii) Recertification is not required when the ownership of a concern that is at least 51% owned by an entity (*i.e.,* tribe, Alaska Native Corporation, or Community Development Corporation) changes to or from a wholly-owned business concern of the same entity, as long as the ultimate owner remains that entity.

Example 1 to paragraph (g)(2)(iii). Indian Tribe X owns 100% of small business ABC. ABC wins an award for a small business set-aside contract. In year two of contract performance, X changes the ownership of ABC so that X owns 100% of a holding company XYZ, Inc., which in turn owns 100% of ABC. This restructuring does not require ABC to recertify its status as a small business because it continues to be 100% owned (indirectly rather than directly) by Indian Tribe X.

(3) * * * A contracting officer may also request size recertification, as he or she deems appropriate, prior to the 120-day point in the fifth year of a long-term contract. * * *

* * * * *

(h) *Follow-on contracts.* * * *

§ 121.406 [Amended]

■ 5. Amend § 121.406 by removing the word ''provided'' and adding in its place the word ''provide'' in paragraph (a) introductory text.

■ 6. Amend § 121.603 by adding paragraph (c)(3) to read as follows:

§ 121.603 How does SBA determine whether a Participant is small for a particular 8(a) BD subcontract?

* * * * *

(c) * * *

(3) Recertification is not required when the ownership of a concern that is at least 51% owned by an entity (*i.e.,* tribe, Alaska Native Corporation, or Community Development Corporation) changes to or from a wholly-owned business concern of the same entity, as long as the ultimate owner remains that entity.

* * * * *

■ 7. Amend § 121.702 by revising paragraph (c)(6) to read as follows:

§ 121.702 What size and eligibility standards are applicable to the SBIR and STTR programs?

* * * * *

(c) * * *

(6) *Size requirement for joint ventures.* Two or more small business concerns may submit an application as a joint venture. The joint venture will qualify as small as long as each concern is small under the size standard for the SBIR program, found at § 121.702(c), or the joint venture meets the exception at § 121.103(h)(3)(ii) for two firms approved to be a mentor and protégé under SBA's All Small Mentor-Protégé Program.

* * * * *

■ 8. Amend § 121.1001 by revising paragraphs (a)(1)(iii), (a)(2)(iii), (a)(3)(iv), (a)(4)(iii), (a)(6)(iv), (a)(7)(iii), (a)(8)(iv), and (a)(9)(iv) to read as follows:

§ 121.1001 Who may initiate a size protest or request a formal size determination?

(a) * * *

(1) * * *

(iii) The SBA Government Contracting Area Director having responsibility for the area in which the headquarters of the protested offeror is located, regardless of the location of a parent company or affiliates, the Director, Office of Government Contracting, or the Associate General Counsel for Procurement Law; and

* * * * *

(2) * * *

(iii) The SBA District Director, or designee, in either the district office serving the geographical area in which the procuring activity is located or the district office that services the apparent successful offeror, the Associate Administrator for Business Development, or the Associate General Counsel for Procurement Law.

* * * * *

(3) * * *

(iv) The responsible SBA Government Contracting Area Director or the Director, Office of Government Contracting, or the SBA's Associate General Counsel for Procurement Law; and

* * * * *

(4) * * *

(iii) The responsible SBA Government Contracting Area Director; the Director, Office of Government Contracting; the Associate Administrator, Investment

Division, or the Associate General Counsel for Procurement Law.

* * * * *

(6) * * *

(iv) The SBA Director, Office of HUBZone, or designee, or the SBA Associate General Counsel for Procurement Law.

* * * * *

(7) * * *

(iii) The responsible SBA Government Contracting Area Director, the Director, Office of Government Contracting, the Associate Administrator for Business Development, or the Associate General Counsel for Procurement Law.

* * * * *

(8) * * *

(iv) The Director, Office of Government Contracting, or designee, or the Associate General Counsel for Procurement Law.

* * * * *

(9) * * *

(iv) The Director, Office of Government Contracting, or designee, or the Associate General Counsel for Procurement Law.

* * * * *

■ 9. Amend § 121.1004 by revising paragraph (a)(2)(ii) and adding paragraph (a)(2)(iii) to read as follows:

§ 121.1004 What time limits apply to size protests?

(a) * * *

(2) * * *

(ii) An order issued against a Multiple Award Contract if the contracting officer requested a size recertification in connection with that order; or

(iii) Except for orders or Blanket Purchase Agreements issued under any Federal Supply Schedule contract, an order or Blanket Purchase Agreement set-aside for small business (*i.e.,* small business set-aside, 8(a) small business, service-disabled veteran-owned small business, HUBZone small business, or women-owned small business) where the underlying Multiple Award Contract was awarded on an unrestricted basis.

* * * * *

■ 10. Amend § 121.1103 by revising paragraph (c)(1)(i) to read as follows:

§ 121.1103 What are the procedures for appealing a NAICS code or size standard designation?

* * * * *

(c) * * *

(1) * * *

(i) Stay the date for the closing of receipt of offers;

* * * * *

PART 124—8(a) BUSINESS DEVELOPMENT/SMALL DISADVANTAGED BUSINESS STATUS DETERMINATIONS

■ 11. The authority citation for part 124 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), 636(j), 637(a), 637(d), 644 and Pub. L. 99–661, Pub. L. 100–656, sec. 1207, Pub. L. 101–37, Pub. L. 101–574, section 8021, Pub. L. 108–87, and 42 U.S.C. 9815.

■ 12. Amend § 124.3 by adding in alphabetical order a definition for ''Follow-on requirement or contract'' to read as follows:

§ 124.3 What definitions are important in the 8(a) BD program?

* * * * *

Follow-on requirement or contract. The determination of whether a particular procurement is a follow-on includes the following considerations:

(1) Whether the scope has changed significantly, requiring meaningful different types of work or different capabilities;

(2) Whether the magnitude or value of the requirement has changed by at least 25 percent; and

(3) Whether the end user of the requirement has changed. As a general guide, if the procurement satisfies at least one of these three conditions, it may be considered a new requirement. Conversely, if the procurement satisfies none of these conditions, it is considered a follow-on procurement. The 25 percent rule, however, cannot be applied rigidly in all cases because by doing so could encourage a result that is inconsistent with the intent of another provision in this part.

* * * * *

■ 13. Amend § 124.105 by revising paragraphs (g) and (i)(2) and (4) to read as follows:

§ 124.105 What does it mean to be unconditionally owned by one or more disadvantaged individuals?

* * * * *

(g) *Ownership of another current or former Participant by an immediate family member.* (1) An individual may not use his or her disadvantaged status to qualify a concern if that individual has an immediate family member who is using or has used his or her disadvantaged status to qualify another concern for the 8(a) BD program and any of the following circumstances exist:

(i) The concerns are connected by any common ownership or management, regardless of amount or position; or

(ii) The concerns have a contractual relationship that was not conducted at arm's length.

Example 1 to paragraph (g)(1). X applies to the 8(a) BD program. X is 95% owned by A and 5% by B, A's father and the majority owner in a former 8(a) Participant. Even though B has no involvement in X, X would be ineligible for the program.

Example 2 to paragraph (g)(1). Y applies to the 8(a) BD program. C owns 100% of Y. However, D, C's sister and the majority owner in a former 8(a) Participant, is acting as a Vice President in Y. Y would be ineligible for the program.

Example 3 to paragraph (g)(1). X seeks to apply to the 8(a) BD program with a primary NAICS code in plumbing. X is 100% owned by A. Z, a former 8(a) participant with a primary industry in general construction, is owned 100% by B, A's brother. For general construction jobs, Z has subcontracted plumbing work to X in the past at normal commercial rates. Subcontracting work at normal commercial rates would not preclude X from being admitted to the 8(a) BD program. X would be eligible for the program.

(2) If the AA/BD approves an application under paragraph (g)(1) of this section, SBA will, as part of its annual review, assess whether the firm continues to operate independently of the other current or former 8(a) concern of an immediate family member. SBA may initiate proceedings to terminate a firm from further participation in the 8(a) BD program if it is apparent that there are connections between the two firms that were not disclosed to the AA/BD at the time of application or that came into existence after program admittance.

* * * * *

(i) * * *

(2) Prior approval by the AA/BD is not needed where all non-disadvantaged individual (or entity) owners involved in the change of ownership own no more than a 20 percent interest in the concern both before and after the transaction, the transfer results from the death or incapacity due to a serious, long-term illness or injury of a disadvantaged principal, or the disadvantaged individual or entity in control of the Participant will increase the percentage of its ownership interest. The concern must notify SBA within 60 days of such a change in ownership.

Example 1 to paragraph (i)(2). Disadvantaged individual A owns 90% of 8(a) Participant X; non-disadvantaged individual B owns 10% of X. In order to raise additional capital, X seeks to change its ownership structure such that A would own 80%, B would own 10% and C would own 10%. X can accomplish this change in ownership without prior SBA approval. Non-disadvantaged owner B is not involved in the transaction and non-disadvantaged individual C owns less than 20% of X both before and after the transaction.

Example 2 to paragraph (i)(2). Disadvantaged individual C owns 60% of 8(a) Participant Y; non-disadvantaged

individual D owns 30% of Y; and non-disadvantaged individual E owns 10% of Y. C seeks to transfer 5% of Y to E. Prior SBA approval is not needed. Although non-disadvantaged individual D owns more than 20% of Y, D is not involved in the transfer. Because the only non-disadvantaged individual involved in the transfer, E, owns less than 20% of Y both before and after the transaction, prior approval is not needed.

Example 3 to paragraph (i)(2). Disadvantaged individual A owns 85% of 8(a) Participant X; non-disadvantaged individual B owns 15% of X. A seeks to transfer 15% of X to B. Prior SBA approval is needed. Although B, the non-disadvantaged owner of X, owns less than 20% of X prior to the transaction, prior approval is needed because B would own more than 20% after the transaction.

Example 4 to paragraph (i)(2). ANC A owns 60% of 8(a) Participant X; non-disadvantaged individual B owns 40% of X. X seeks to transfer 15% to A. Prior SBA approval is not needed. Although a non-disadvantaged individual who is involved in the transaction, B, owns more than 20% of X both before and after the transaction, SBA approval is not needed because the change only increases the percentage of A's ownership interest in X.

* * * * *

(4) Where a Participant requests a change of ownership or business structure, and proceeds with the change prior to receiving SBA approval (or where a change of ownership results from the death or incapacity of a disadvantaged individual for which a request prior to the change in ownership could not occur), SBA may suspend the Participant from program benefits pending resolution of the request. If the change is approved, the length of the suspension will be restored to the Participant's program term in the case of death or incapacity, or if the firm requested prior approval and waited 60 days for SBA approval.

* * * * *

■ 14. Amend § 124.109 by:
■ a. Revising the section heading;
■ b. Adding paragraph (a)(7);
■ c. Revising paragraph (c)(3)(ii);
■ d. Adding paragraphs (c)(3)(iv) and (c)(4)(iii)(C); and
■ e. Revising paragraphs (c)(6)(iii) and (c)(7)(ii).

The revisions and additions to read as follows:

§ 124.109 Do Indian tribes and Alaska Native Corporations have any special rules for applying to and remaining eligible for the 8(a) BD program?

(a) * * *

(7) Notwithstanding § 124.105(i), where an ANC merely reorganizes its ownership of a Participant in the 8(a) BD program by inserting or removing a wholly-owned business entity between the ANC and the Participant, the Participant need not request a change of ownership from SBA. The Participant must, however, notify SBA of the change within 30 days of the transfer.

* * * * *

(c) * * *

(3) * * *

(ii) A Tribe may not own 51% or more of another firm which, either at the time of application or within the previous two years, has been operating in the 8(a) program under the same primary NAICS code as the applicant. A Tribe may, however, own a Participant or other applicant that conducts or will conduct secondary business in the 8(a) BD program under the NAICS code which is the primary NAICS code of the applicant concern.

(A) Once an applicant is admitted to the 8(a) BD program, it may not receive an 8(a) sole source contract that is a follow-on contract to an 8(a) contract that was performed immediately previously by another Participant (or former Participant) owned by the same Tribe. For purposes of this paragraph, the same primary NAICS code means the six-digit NAICS code having the same corresponding size standard.

(B) If the primary NAICS code of a tribally-owned Participant is changed pursuant to § 124.112(e), the tribe can submit an application and qualify another firm owned by the tribe for participation in the 8(a) BD program under the NAICS code that was the previous primary NAICS code of the Participant whose primary NAICS code was changed.

Example 1 to paragraph (c)(3)(ii)(B). Tribe X owns 100% of 8(a) Participant A. A entered the 8(a) BD program with a primary NAICS code of 236115, New Single-Family Housing Construction (except For-Sale Builders). After four years in the program, SBA noticed that the vast majority of A's revenues were in NAICS Code 237310, Highway, Street, and Bridge Construction, and notified A that SBA intended to change its primary NAICS code pursuant to § 124.112(e). A agreed to change its primary NAICS Code to 237310. Once the change is finalized, Tribe X can immediately submit a new application to qualify another firm that it owns for participation in the 8(a) BD program with a primary NAICS Code of 236115.

* * * * *

(iv) Notwithstanding § 124.105(i), where a Tribe merely reorganizes its ownership of a Participant in the 8(a) BD program by inserting or removing a wholly-owned business entity between the Tribe and the Participant, the Participant need not request a change of ownership from SBA. The Participant must, however, notify SBA of the change within 30 days of the transfer.

* * * * *

(4) * * *

(iii) * * *

(C) Because an individual may be responsible for the management and daily business operations of two tribally-owned concerns, the full-time devotion requirement does not apply to tribally-owned applicants and Participants.

* * * * *

(6) * * *

(iii) The Tribe, a tribally-owned economic development corporation, or other relevant tribally-owned holding company vested with the authority to oversee tribal economic development or business ventures has made a firm written commitment to support the operations of the applicant concern and it has the financial ability to do so.

(7) * * *

(ii) The officers, directors, and all shareholders owning an interest of 20% or more (other than the tribe itself) of a tribally-owned applicant or Participant must demonstrate good character (*see* § 124.108(a)) and cannot fail to pay significant Federal obligations owed to the Federal Government (*see* § 124.108(e)).

■ 15. Amend § 124.110 by revising the section heading and paragraph (e) to read as follows:

§ 124.110 Do Native Hawaiian Organizations (NHOs) have any special rules for applying to and remaining eligible for the 8(a) BD program?

* * * * *

(e) An NHO cannot own 51% or more of another firm which, either at the time of application or within the previous two years, has been operating in the 8(a) program under the same primary NAICS code as the applicant. An NHO may, however, own a Participant or an applicant that conducts or will conduct secondary business in the 8(a) BD program under the same NAICS code that a current Participant owned by the NHO operates in the 8(a) BD program as its primary NAICS code.

(1) Once an applicant is admitted to the 8(a) BD program, it may not receive an 8(a) sole source contract that is a follow-on contract to an 8(a) contract that was performed immediately previously by another Participant (or former Participant) owned by the same NHO. For purposes of this paragraph, the same primary NAICS code means the six-digit NAICS code having the same corresponding size standard.

(2) If the primary NAICS code of a Participant owned by an NHO is changed pursuant to § 124.112(e), the NHO can submit an application and qualify another firm owned by the NHO for participation in the 8(a) BD program

under the NAICS code that was the previous primary NAICS code of the Participant whose primary NAICS code was changed.

* * * * *

■ 16. Amend § 124.111 by revising the section heading, adding paragraph (c)(3), and revising paragraph (d) to read as follows:

§ 124.111 Do Community Development Corporations (CDCs) have any special rules for applying to and remaining eligible for the 8(a) BD program?

* * * * *

(c) * * *

(3) Notwithstanding § 124.105(i), where a CDC merely reorganizes its ownership of a Participant in the 8(a) BD program by inserting or removing a wholly-owned business entity between the CDC and the Participant, the Participant need not request a change of ownership from SBA. The Participant must, however, notify SBA of the change within 30 days of the transfer.

(d) A CDC cannot own 51% or more of another firm which, either at the time of application or within the previous two years, has been operating in the 8(a) program under the same primary NAICS code as the applicant. A CDC may, however, own a Participant or an applicant that conducts or will conduct secondary business in the 8(a) BD program under the same NAICS code that a current Participant owned by the CDC operates in the 8(a) BD program as its primary SIC code.

(1) Once an applicant is admitted to the 8(a) BD program, it may not receive an 8(a) sole source contract that is a follow-on contract to an 8(a) contract that was performed immediately previously by another Participant (or former Participant) owned by the same CDC. For purposes of this paragraph, the same primary NAICS code means the six-digit NAICS code having the same corresponding size standard.

(2) If the primary NAICS code of a Participant owned by a CDC is changed pursuant to § 124.112(e), the CDC can submit an application and qualify another firm owned by the CDC for participation in the 8(a) BD program under the NAICS code that was the previous primary NAICS code of the Participant whose primary NAICS code was changed.

* * * * *

■ 17. Amend § 124.112 by revising paragraph (d)(5), redesignating paragraph (e)(2)(iv) as paragraph (e)(2)(v), and adding a new paragraph (e)(2)(iv).

The revision and addition read as follows:

§ 124.112 What criteria must a business meet to remain eligible to participate in the 8(a) BD program?

* * * * *

(d) * * *

(5) The excessive withdrawal analysis does not apply to Participants owned by Tribes, ANCs, NHOs, or CDCs where a withdrawal is made for the benefit of the Tribe, ANC, NHO, CDC or the native or shareholder community. It does, however, apply to withdrawals from a firm owned by a Tribe, ANC, NHO, or CDC that do not benefit the relevant entity or community. Thus, if funds or assets are withdrawn from an entity-owned Participant for the benefit of a non-disadvantaged manager or owner that exceed the withdrawal thresholds, SBA may find that withdrawal to be excessive. However, a non-disadvantaged minority owner may receive a payout in excess of the excessive withdrawal amount if it is a pro rata distribution paid to all shareholders (*i.e.,* the only way to increase the distribution to the Tribe, ANC, NHO or CDC is to increase the distribution to all shareholders) and it does not adversely affect the business development of the Participant.

Example 1 to paragraph (d)(5). Tribally-owned Participant X pays $1,000,000 to a non-disadvantaged manager. That would be deemed an excessive withdrawal.

Example 2 to paragraph (d)(5). ANC-owned Participant Y seeks to distribute $550,000 to the ANC and $450,000 to non-disadvantaged individual A based on their 55%/45% ownership interests. Because the distribution is based on the pro rata share of ownership, this would not be prohibited as an excessive withdrawal unless SBA determined that Y would be adversely affected.

(e) * * *

(2) * * *

(iv) A Participant may appeal a district office's decision to change its primary NAICS code to SBA's Associate General Counsel for Procurement Law (AGC/PL) within 10 business days of receiving the district office's final determination. The AGC/PL will examine the record, including all information submitted by the Participant in support of its position as to why the primary NAICS code contained in its business plan continues to be appropriate despite performing more work in another NAICS code, and issue a final agency decision within 15 business days of receiving the appeal.

* * * * *

■ 18. Amend § 124.203 by revising the first two sentences and adding a new third sentence to read as follows:

§ 124.203 What must a concern submit to apply to the 8(a) BD program?

Each 8(a) BD applicant concern must submit information and supporting documents required by SBA when applying for admission to the 8(a) BD program. This information may include, but not be limited to, financial data and statements, copies of filed Federal personal and business tax returns, individual and business bank statements, personal history statements, and any additional information or documents SBA deems necessary to determine eligibility. Each individual claiming disadvantaged status must also submit a signed IRS Form 4506T, Request for Copy or Transcript of TAX Form, to SBA. * * *

■ 19. Amend § 124.204 by adding a sentence to the end of paragraph (a) to read as follows:

§ 124.204 How does SBA process applications for 8(a) BD program admission?

(a) * * * Where during its review SBA requests clarifying, revised or other information from the applicant, SBA's processing time for the application will be suspended pending the receipt of such information.

* * * * *

■ 20. Revise § 124.207 to read as follows:

§ 124.207 Can an applicant reapply for admission to the 8(a) BD program?

A concern which has been declined for 8(a) BD program participation may submit a new application for admission to the program at any time after 90 days from the date of the Agency's final decision to decline.

§ 124.301 [Redesignated as § 124.300]

■ 21. Redesignate § 124.301 as § 124.300.

■ 22. Add new § 124.301 to read as follows:

§ 124.301 Voluntary withdrawal or voluntary early graduation.

(a) A Participant may voluntarily withdraw from the 8(a) BD program at any time prior to the expiration of its program term. Where a Participant has substantially achieved the goals and objectives set forth in its business plan, it may elect to voluntarily early graduate from the 8(a) BD program.

(b) To initiate withdrawal or early graduation from the 8(a) BD program, a Participant must notify its servicing SBA district office of its intent to do so in writing. Once the SBA servicing district office processes the request and the District Director recognizes the withdrawal or early graduation, the

Participant is no longer eligible to receive any 8(a) BD program assistance.

■ 23. Amend § 124.304 by revising the paragraph (d) subject heading and adding a sentence at the end of paragraph (d) to read as follows:

§ 124.304 What are the procedures for early graduation and termination?

* * * * *

(d) *Notice requirements and effect of decision.* * * * Once the AA/BD issues a decision to early graduate or terminate a Participant, the Participant will be immediately suspended from receiving further program assistance until the determination becomes the final agency decision.

* * * * *

■ 24. Amend § 124.305 by revising paragraphs (h)(1)(ii) and (iv), and adding paragraph (h)(1)(v) to read as follows:

§ 124.305 What is suspension and how is a Participant suspended from the 8(a) BD program?

* * * * *

(h) * * *

(1) * * *

(ii) A disadvantaged individual who is involved in controlling the day-to-day management and control of the Participant is called to active military duty by the United States, his or her participation in the firm's management and daily business operations is critical to the firm's continued eligibility, the Participant does not designate another disadvantaged individual to control the concern during the call-up period, and the Participant requests to be suspended during the call-up period;

* * * * *

(iv) Federal appropriations for one or more Federal departments or agencies have lapsed, a Participant would lose an 8(a) sole source award due to the lapse in appropriations (*e.g.,* SBA has previously accepted an offer for a sole source 8(a) award on behalf of the Participant or an agency could not offer a sole source 8(a) requirement to the program on behalf of the Participant due to the lapse in appropriations, and the Participant's program term would end during the lapse), and the Participant elects to suspend its participation in the 8(a) BD program during the lapse in Federal appropriations; or

(v) A Participant has not submitted a business plan to its SBA servicing office within 60 days after program admission.

* * * * *

■ 25. Amend § 124.402 by revising paragraph (b) to read as follows:

§ 124.402 How does a Participant develop a business plan?

* * * * *

(b) *Submission of initial business plan.* Each Participant must submit a business plan to its SBA servicing office as soon as possible after program admission. SBA will suspend a Participant from receiving 8(a) BD program benefits, including 8(a) contracts, if it has not submitted its business plan to the servicing district office within 60 days after program admission.

* * * * *

■ 26. Amend § 124.501 by redesignating paragraphs (g) through (i) as paragraphs (h) through (j), respectively, and by adding new paragraphs (g) and (k) to read as follows:

§ 124.501 What general provisions apply to the award of 8(a) contracts?

* * * * *

(g) Before a Participant may be awarded either a sole source or competitive 8(a) contract, SBA must determine that the Participant is eligible for award. SBA will determine eligibility at the time of its acceptance of the underlying requirement into the 8(a) BD program for a sole source 8(a) contract, and after the apparent successful offeror is identified for a competitive 8(a) contract. Eligibility is based on 8(a) BD program criteria, including whether the Participant:

(1) Qualifies as a small business under the size standard corresponding to the NAICS code assigned to the requirement;

(2) Is in compliance with any applicable competitive business mix targets established or remedial measure imposed by § 124.509 that does not include the denial of future sole source 8(a) contracts or 8(a) contracts generally, as applicable;

(3) Complies with the continued eligibility reporting requirements set forth in § 124.112(b);

(4) Has a bona fide place of business in the applicable geographic area if the procurement is for construction;

(5) Has not received 8(a) contracts in excess of the dollar limits set forth in § 124.519 for a sole source 8(a) procurement;

(6) Has complied with the provisions of § 124.513(c) and (d) if it is seeking a sole source 8(a) award through a joint venture; and

(7) Can demonstrate that it, together with any similarly situated entity, will meet the limitations on subcontracting provisions set forth in § 124.510.

* * * * *

(k) In order to be awarded a sole source or competitive 8(a) construction contract, a Participant must have a bona fide place of business within the applicable geographic location determined by SBA. This will generally be the geographic area serviced by the SBA district office in which the work will be performed. SBA may determine that a Participant with a bona fide place of business within the entire state (if the state is serviced by more than one SBA district office), a contiguous SBA district office (in the same or another state), or another nearby area is eligible for the award of an 8(a) construction contract.

(1) A Participant may have bona fide places of business in more than one location.

(2) In order for a Participant to establish a bona fide place of business in a particular geographic location, the SBA district office serving the geographic area of that location must determine if that location in fact qualifies as a bona fide place of business under SBA's requirements.

(i) A Participant must submit a request for a bona fide business determination to the SBA district office servicing it. Such request may, but need not, relate to a specific 8(a) requirement. In order to apply to a specific competitive 8(a) solicitation, such request must be submitted at least 20 working days before initial offers that include price are due.

(ii) The servicing district office will immediately forward the request to the SBA district office serving the geographic area of the particular location for processing. Within 10 working days of receipt of the submission, the reviewing district office will conduct a site visit, if practicable. If not practicable, the reviewing district office will contact the Participant within such 10-day period to inform the Participant that the reviewing office has received the request and may ask for additional documentation to support the request.

(iii) In connection with a specific competitive solicitation, the reviewing office will make a determination whether or not the Participant has a bona fide place of business in its geographical area within 5 working days of a site visit or within 15 working days of its receipt of the request from the servicing district office if a site visit is not practical in that timeframe. If the request is not related to a specific procurement, the reviewing office will make a determination within 30 working days of its receipt of the request from the servicing district office, if practicable.

(3) The effective date of a bona fide place of business is the date that the

evidence (paperwork) shows that the business in fact regularly maintained its business at the new geographic location.

(4) In order for a Participant to be eligible to submit an offer for an 8(a) procurement limited to a specific geographic area, it must receive from SBA a determination that it has a bona fide place of business within that area prior to submitting its offer for the procurement.

(5) Once a Participant has established a bona fide place of business, the Participant may change the location of the recognized office without prior SBA approval. However, the Participant must notify SBA and provide documentation demonstrating an office at that new location within 30 days after the move. Failure to timely notify SBA will render the Participant ineligible for new 8(a) construction procurements limited to that geographic area.

■ 27. Amend § 124.503 by:

■ a. Removing the phrase ''in § 124.507(b)(2)'' and adding in its place the phrase ''in § 124.501(g)'' in paragraph (a)(1);

■ b. Redesignating paragraphs (e) through (j) as paragraphs (f) through (k), respectively;

■ c. Adding a new paragraph (e);

■ d. Revising the introductory text of the newly redesignated paragraph (h);

■ e. Adding the phrase ''or BPA'' after the phrase ''BOA'', wherever it appears, in the newly redesignated paragraphs (h)(1) through (4);

■ f. Revising newly redesignated paragraph (i)(1)(iii);

■ g. Adding a sentence at the end of newly redesignated paragraph (i)(1)(iv); and

■ h. Revising newly redesignated paragraph (i)(2)(iv).

The additions and revisions read as follows:

§ 124.503 How does SBA accept a procurement for award through the 8(a) BD program?

* * * * *

(e) *Withdrawal/substitution of offered requirement or Participant.* After SBA has accepted a requirement for award as a sole source 8(a) contract on behalf of a specific Participant (whether nominated by the procuring agency or identified by SBA for an open requirement), if the procuring agency believes that the identified Participant is not a good match for the procurement—including for such reasons as the procuring agency finding the Participant non-responsible or the negotiations between the procuring agency and the Participant otherwise failing—the procuring agency may seek to substitute another Participant for the originally identified Participant. The procuring agency must inform SBA of its concerns regarding the originally identified Participant and identify whether it believes another Participant could fulfill its needs.

(1) If the procuring agency and SBA agree that another Participant can fulfill its needs, the procuring agency will withdraw the original offering and reoffer the requirement on behalf of another 8(a) Participant. SBA will then accept the requirement on behalf of the newly identified Participant and authorize the procuring agency to negotiate directly with that Participant.

(2) If the procuring agency and SBA agree that another Participant cannot fulfill its needs, the procuring agency will withdraw the original offering letter and fulfill its needs outside the 8(a) BD program.

(3) If the procuring agency believes that another Participant cannot fulfill its needs, but SBA does not agree, SBA may appeal that decision to the head of the procuring agency pursuant to § 124.505(a)(2).

* * * * *

(h) *Basic Ordering Agreements (BOAs) and Blanket Purchase Agreements (BPAs).* Neither a Basic Ordering Agreement (BOA) nor a Blanket Purchase Agreement (BPA) is a contract under the FAR. *See* 48 CFR 16.703(a). Each order to be issued under a BOA or BPA is an individual contract. As such, the procuring activity must offer, and SBA must accept, each task order under a BOA or BPA in addition to offering and accepting the BOA or BPA itself.

* * * * *

(i)

(1) * * *

(iii) A concern awarded a task or delivery order contract or Multiple Award Contract that was set-aside exclusively for 8(a) Program Participants, partially set-aside for 8(a) Program Participants or reserved solely for 8(a) Program Participants may generally continue to receive new orders even if it has grown to be other than small or has exited the 8(a) BD program, and agencies may continue to take SDB credit toward their prime contracting goals for orders awarded to 8(a) Participants. However, a firm will be ineligible for the award of an order if the procuring agency asks contract holders to recertify their 8(a) BD status in connection with a specific order and the firm is unable to do so. Where a contracting officer asks contract holders to recertify their 8(a) BD status in connection with a specific order, a firm must be an eligible Participant in accordance with § 124.501(g) as of the initial date specified for the receipt of offers contained in the order solicitation, or at the date of award of the order if there is no solicitation.

(iv) * * * To be eligible for the award of a sole source order, a concern must be a current Participant in the 8(a) BD program at the time of award.

(2) * * *

(iv) SBA must verify that a concern is an eligible 8(a) Participant in accordance with § 124.501(g) as of the initial date specified for the receipt of offers contained in the order solicitation, or at the date of award of the order if there is no solicitation. If a concern has exited the 8(a) BD program prior to that date, it will be ineligible for the award of the order.

* * * * *

■ 28. Amend § 124.504 by:

■ a. Revising the section heading and paragraph (b);

■ b. Removing the term ''Simplified Acquisition Procedures'' and adding in its place the phrase ''the simplified acquisition threshold (as defined in the FAR at 48 CFR 2.101)'' in paragraph (c) introductory text;

■ c. Removing the word ''will'' and adding in its place the word ''may'' in paragraph (c)(1)(ii)(C);

■ d. Revising the subject heading for paragraph (d) and paragraphs (d)(1) introductory text and (d)(4).

The revisions read as follows:

§ 124.504 What circumstances limit SBA's ability to accept a procurement for award as an 8(a) contract, and when can a requirement be released from the 8(a) BD program?

* * * * *

(b) *Competition prior to offer and acceptance.* The procuring activity competed a requirement among 8(a) Participants prior to offering the requirement to SBA and did not clearly evidence its intent to conduct an 8(a) competitive acquisition.

* * * * *

(d) *Release for non-8(a) or limited 8(a) competition.* (1) Except as set forth in paragraph (d)(4) of this section, where a procurement is awarded as an 8(a) contract, its follow-on requirement must remain in the 8(a) BD program unless SBA agrees to release it for non-8(a) competition. Additionally, SBA must agree to release any follow-on requirement where a procuring agency seeks to reprocure that requirement through a pre-existing limited contracting vehicle which is not available to all 8(a) BD Program Participants (*e.g.,* any multiple award or Governmentwide acquisition contract, whether or not the underlying MAC or GWAC is itself an 8(a) contract), and the

previous/current 8(a) award was not so limited. If a procuring agency would like to fulfill a follow-on requirement outside of the 8(a) BD program, it must make a written request to and receive the concurrence of the AA/BD to do so. In determining whether to release a requirement from the 8(a) BD program, SBA will consider:

* * * * *

(4) The requirement that a follow-on procurement must be released from the 8(a) BD program in order for it to be fulfilled outside the 8(a) BD program does not apply:

(i) Where previous orders were offered to and accepted for the 8(a) BD program pursuant to § 124.503(i)(2); or

(ii) Where a procuring agency will use a mandatory source (*see* FAR Subparts 8.6 and 8.7). In such a case, the procuring agency must notify SBA at least 30 days prior to the end of the contract or order.

■ 29. Amend § 124.505 by:

■ a. Removing the word ''and'' at the end of paragraph (a)(2);

■ b. Redesignating paragraph (a)(3) as paragraph (a)(4); and

■ c. Adding new paragraph (a)(3).

The addition reads as follows:

§ 124.505 When will SBA appeal the terms or conditions of a particular 8(a) contract or a procuring activity decision not to use the 8(a) BD program?

(a) * * *

(3) A decision by a contracting officer that a particular procurement is a new requirement that is not subject to the release requirements set forth in § 124.504(d); and

* * * * *

■ 30. Amend § 124.507 by:

■ a. Revising paragraph (b)(2);

■ b. Removing paragraph (b)(3);

■ c. Redesignating paragraphs (b)(4) through (6) as paragraphs (b)(3) through (5), respectively;

■ d. Removing paragraph (c)(1);

■ e. Redesignating paragraphs (c)(2) and (3) as paragraphs (c)(1) and (2), respectively; and

■ f. Revising newly redesignated paragraph (c)(1).

The revisions read as follows:

§ 124.507 What procedures apply to competitive 8(a) procurements?

* * * * *

(b) * * *

(2) SBA determines a Participant's eligibility pursuant to § 124.501(g).

* * * * *

(c) * * *

(1) *Construction competitions.* Based on its knowledge of the 8(a) BD portfolio, SBA will determine whether a competitive 8(a) construction requirement should be competed among only those Participants having a bona fide place of business within the geographical boundaries of one or more SBA district offices, within a state, or within the state and nearby areas. Only those Participants with bona fide places of business within the appropriate geographical boundaries are eligible to submit offers.

* * * * *

■ 31. Amend § 124.509 by:

■ a. Removing the word ''maximum'' and adding in its place the words ''good faith'' in paragraph (a)(1);

■ b. Removing the words ''substantial and sustained'' and adding in their place the words ''good faith'' in paragraph (a)(2); and

■ c. Revising paragraph (e).

The revision reads as follows:

§ 124.509 What are non-8(a) business activity targets?

* * * * *

(e) *Waiver of sole source prohibition.* (1) SBA may waive the requirement prohibiting a Participant from receiving further sole source 8(a) contracts when a Participant does not meet its non-8(a) business activity target where a denial of a sole source contract would cause severe economic hardship on the Participant so that the Participant's survival may be jeopardized, or where extenuating circumstances beyond the Participant's control caused the Participant not to meet its non-8(a) business activity target.

(2) SBA may waive the requirement prohibiting a Participant from receiving further sole source 8(a) contracts when the Participant does not meet its non-8(a) business activity target where the head of a procuring activity represents to the SBA that award of a sole source 8(a) contract to the Participant is needed to achieve significant interests of the Government.

(3) The decision to grant or deny a request for a waiver is at SBA's discretion, and no appeal may be taken with respect to that decision.

(4) A waiver generally applies to a specific sole source opportunity. If SBA grants a waiver with respect to a specific procurement, the firm will be able to self-market its capabilities to the applicable procuring activity with respect to that procurement. If the Participant seeks an additional sole source opportunity, it must request a waiver with respect to that specific opportunity. Where, however, a Participant can demonstrate that the same extenuating circumstances beyond its control affect its ability to receive specific multiple 8(a) contracts, one waiver can apply to those multiple contract opportunities.

■ 32. Amend § 124.513 by revising paragraphs (c)(4) and (e) to read as follows:

§ 124.513 Under what circumstances can a joint venture be awarded an 8(a) contract?

* * * * *

(c) * * *

(4) Stating that the 8(a) Participant(s) must receive profits from the joint venture commensurate with the work performed by the 8(a) Participant(s), or a percentage agreed to by the parties to the joint venture whereby the 8(a) Participant(s) receive profits from the joint venture that exceed the percentage commensurate with the work performed by the 8(a) Participant(s);

* * * * *

(e) *Prior approval by SBA.* (1) When a joint venture between one or more 8(a) Participants seeks a sole source 8(a) award, SBA must approve the joint venture prior to the award of the sole source 8(a) contract. SBA will not approve joint ventures in connection with competitive 8(a) awards.

(2) Where a joint venture has been established for one 8(a) contract, the joint venture may receive additional 8(a) contracts provided the parties create an addendum to the joint venture agreement setting forth the performance requirements for each additional award (and provided any contract is awarded within two years of the first award as set forth in § 121.103(h)). If an additional 8(a) contract is a sole source award, SBA must also approve the addendum prior to contract award.

* * * * *

■ 33. Amend § 124.515 by revising paragraph (d) to read as follows:

§ 124.515 Can a Participant change its ownership or control and continue to perform an 8(a) contract, and can it transfer performance to another firm?

* * * * *

(d) SBA determines the eligibility of an acquiring Participant under paragraph (b)(2) of this section by referring to the items identified in § 124.501(g) and deciding whether at the time of the request for waiver (and prior to the transaction) the acquiring Participant is an eligible concern with respect to each contract for which a waiver is sought. As part of the waiver request, the acquiring concern must certify that it is a small business for the size standard corresponding to the NAICS code assigned to each contract for which a waiver is sought. SBA will not grant a waiver for any contract if the work to be performed under the contract is not similar to the type of work

previously performed by the acquiring concern.

* * * * *

■ 34. Amend § 124.519 by:

■ a. Revising paragraph (a);

■ b. Removing paragraph (c);

■ c. Redesignating paragraph (b) as paragraph (c); and

■ d. Adding a new paragraph (b).

The revision and addition read as follows:

§ 124.519 Are there any dollar limits on the amount of 8(a) contracts that a Participant may receive?

(a) A Participant (other than one owned by an Indian Tribe, ANC, NHO, or CDC) may not receive sole source 8(a) contract awards where it has received a combined total of competitive and sole source 8(a) contracts in excess of $100,000,000 during its participation in the 8(a) BD program.

(b) In determining whether a Participant has reached the limit identified in paragraph (a) of this section, SBA:

(1) Looks at the 8(a) revenues a Participant has actually received, not projected 8(a) revenues that a Participant might receive through an indefinite delivery or indefinite quantity contract, a multiple award contract, or options or modifications; and

(2) Will not consider 8(a) contracts awarded under the Simplified Acquisition Threshold.

* * * * *

■ 35. Revise § 124.520 to read as follows:

§ 124.520 Can 8(a) BD Program Participants participate in SBA's Mentor-Protégé program?

(a) An 8(a) BD Program Participant, as any other small business, may participate in SBA's All Small Mentor-Protégé Program authorized under § 125.9 of this chapter.

(b) In order for a joint venture between a protégé and its SBA-approved mentor to receive the exclusion from affiliation with respect to a sole source or competitive 8(a) contract, the joint venture must meet the requirements set forth in § 124.513(c) and (d).

PART 125—GOVERNMENT CONTRACTING PROGRAMS

■ 36. The authority citation for part 125 continues to read as follows:

Authority: 15 U.S.C. 632(p), (q); 634(b)(6); 637; 644; 657(f); 657q; and 657s; 38 U.S.C. 501 and 8127.

■ 37. Amend § 125.2 by adding paragraph (g) to read as follows:

§ 125.2 What are SBA's and the procuring agency's responsibilities when providing contracting assistance to small businesses?

* * * * *

(g) *Past performance and experience.* (1) In the case of a solicitation for a bundled contract, a consolidated contract, or a multiple award contract above the substantial bundling threshold of the Federal agency, the head of the agency must consider the past performance, capabilities and experience of each first tier subcontractor that is part of the team as the capabilities and past performance of the small business prime contractor when evaluating an offer of a small business prime contractor that includes a proposed team of small business subcontractors.

(2) For other solicitations, based on the circumstances of the procurement, the agency may consider the past performance, capabilities and experience of each first tier subcontractor that is part of the team as the capabilities and past performance of the small business prime contractor.

■ 38. Amend § 125.3 by adding a sentence to the end of paragraph (b)(2) to read as follows:

§ 125.3 What types of subcontracting assistance are available to small businesses?

* * * * *

(b) * * *

(2) * * * This applies whether the firm qualifies as a small business concern for the size standard corresponding to the NAICS code assigned to the contract, or is deemed to be treated as a small business concern by statute (*see e.g.,* 43 U.S.C. 1626(e)(4)(B)).

* * * * *

■ 39. Amend § 125.5 by:

■ a. Revising the third sentence of paragraph (a)(1);

■ b. Removing the phrase ''$100,000 or less, or in accordance with Simplified Acquisition Threshold procedures'' and adding in its place the phrase ''Less than the Simplified Acquisition Threshold'' in paragraph (g);

■ c. Removing the phrase ''Between $100,000 and $25 million'' and adding in its place the phrase ''Between the Simplified Acquisition Threshold and $25 million'' in paragraph (g);

■ d. Removing the term ''$100,000'' and adding in its place ''the simplified acquisition threshold'' in paragraphs (h) and (i).

The revision reads as follows:

§ 125.5 What is the Certificate of Competency Program?

(a) * * *

(1) * * * The COC Program is applicable to all Government procurement actions, with the exception of 8(a) sole source awards but including Multiple Award Contracts and orders placed against Multiple Award Contracts, where the contracting officer has used any issues of capacity or credit (responsibility) to determine suitability for an award. * * *

* * * * *

■ 40. Amend § 125.6 by revising the paragraph (b) introductory text and adding example 3 to paragraph (b) to read as follows:

§ 125.6 What are the prime contractor's limitations on subcontracting?

* * * * *

(b) *Mixed contracts.* Where a contract integrates any combination of services, supplies, or construction, the contracting officer shall select the appropriate NAICS code as prescribed in § 121.402(b) of this chapter. The contracting officer's selection of the applicable NAICS code is determinative as to which limitation on subcontracting and performance requirement applies. Based on the NAICS code selected, the relevant limitation on subcontracting requirement identified in paragraphs (a)(1) through (4) of this section will apply only to that portion of the contract award amount. In no case shall more than one limitation on subcontracting requirement apply to the same contract.

* * * * *

Example 3 to paragraph (b). A procuring activity is acquiring both services and general construction through a small business set-aside. The total value of the requirement is $10,000,000, with the construction portion comprising $8,000,000, and the services portion comprising $2,000,000. The contracting officer appropriately assigns a construction NAICS code to the requirement. The 85% limitation on subcontracting identified in paragraph (a)(3) would apply to this procurement. Because the services portion of the contract is excluded from consideration, the relevant amount for purposes of calculating the limitation on subcontracting requirement is $8,000,000. As such, the prime contractor cannot subcontract more than $6,800,000 to non-similarly situated entities, and the prime and/or similarly situated entities must perform at least $1,200,000.

* * * * *

■ 41. Amend § 125.8 by revising paragraphs (b)(2)(iv), (xi), and (xii), (e), and (h)(2) to read as follows:

§ 125.8 What requirements must a joint venture satisfy to submit an offer for a procurement or sale set aside or reserved for small business?

* * * * *

(b) * * *

(2) * * *

(iv) Stating that the small business participant(s) must receive profits from the joint venture commensurate with the work performed by them, or a percentage agreed to by the parties to the joint venture whereby the small business participant(s) receive profits from the joint venture that exceed the percentage commensurate with the work performed by them;

* * * * *

(xi) Stating that annual performance-of-work statements required by paragraph (h)(1) must be submitted to SBA and the relevant contracting officer not later than 45 days after each operating year of the joint venture; and

(xii) Stating that the project-end performance-of-work required by paragraph (h)(2) must be submitted to SBA and the relevant contracting officer no later than 90 days after completion of the contract.

* * * * *

(e) *Past performance and experience.* When evaluating the past performance, experience, business systems and certifications of an entity submitting an offer for a contract set aside or reserved for small business as a joint venture established pursuant to this section, a procuring activity must consider work done and qualifications held individually by each partner to the joint venture as well as any work done by the joint venture itself previously.

* * * * *

(h) * * *

(2) At the completion of every contract set aside or reserved for small business that is awarded to a joint venture between a protégé small business and a mentor authorized by § 125.9, and upon request by the SBA or the relevant contracting officer, the small business partner to the joint venture must submit a report to the relevant contracting officer and to the SBA, signed by an authorized official of each partner to the joint venture, explaining how and certifying that the performance of work requirements were met for the contract, and further certifying that the contract was performed in accordance with the provisions of the joint venture agreement that are required under paragraph (b) of this section.

* * * * *

■ 42. Amend § 125.9 by:

■ a. Revising paragraphs (b), (c)(1)(ii), and (c)(2) introductory text;

■ b. Removing paragraph (c)(4);

■ c. Revising paragraphs (d)(1)(iii) introductory text and (d)(1)(iii)(B);

■ d. Adding paragraph (d)(6);

■ e. Removing ''(*e.g.,* management and/or technical assistance, loans and/or equity investments, cooperation on joint venture projects, or subcontracts under prime contracts being performed by the mentor)'' and adding in its place ''(*e.g.,* management and or technical assistance; loans and/or equity investments; bonding; use of equipment; export assistance; assistance as a subcontractor under prime contracts being performed by the protégé; cooperation on joint venture projects; or subcontracts under prime contracts being performed by the mentor)'' in paragraph (e)(1) introductory text.

■ f. Revising paragraph (e)(1)(i);

■ g. Removing the first sentence and revising the new first sentence of paragraph (e)(5);

■ h. Redesignating paragraphs (e)(6) through (8) as paragraphs (e)(7) through (9), respectively;

■ i. Adding new paragraph (e)(6);

■ j. Revising paragraph (f);

■ k. Adding paragraph (g) introductory text; and

■ l. Revising paragraph (g)(4).

The revisions and additions to read as follows:

§ 125.9 What are the rules governing SBA's small business mentor-protégé program?

* * * * *

(b) *Mentors.* Any concern that demonstrates a commitment and the ability to assist small business concerns may act as a mentor and receive benefits as set forth in this section. This includes other than small businesses.

(1) In order to qualify as a mentor, a concern must demonstrate that it:

(i) Is capable of carrying out its responsibilities to assist the protégé firm under the proposed mentor-protégé agreement;

(ii) Does not appear on the Federal list of debarred or suspended contractors; and

(iii) Can impart value to a protégé firm due to lessons learned and practical experience gained or through its knowledge of general business operations and government contracting.

(2) SBA will decline an application if SBA determines that the mentor does not possess good character or a favorable financial position, employs or otherwise controls the managers of the protégé, or is otherwise affiliated with the protégé. Once approved, SBA may terminate the mentor-protégé agreement if the mentor does not possess good character or a favorable financial position, was affiliated with the protégé at time of application, or is affiliated with the protégé for reasons other than the mentor-protégé agreement or assistance provided under the agreement.

(3) In order for SBA to agree to allow a mentor to have more than one protégé at time, the mentor and proposed additional protégé must demonstrate that the added mentor-protégé relationship will not adversely affect the development of either protégé firm (*e.g.,* the second firm may not be a competitor of the first firm).

(i) A mentor that has more than one protégé cannot submit competing offers in response to a solicitation for a specific procurement through separate joint ventures with different protégés.

(ii) A mentor generally cannot have more than three protégés at one time. However, the first two mentor-protégé relationships approved by SBA between a specific mentor and a small business that has its principal office located in the Commonwealth of Puerto Rico do not count against the limit of three proteges that a mentor can have at one time.

(c) * * *

(1) * * *

(ii) Where a small business seeks to qualify as a protégé in a secondary NAICS code, the firm must demonstrate how the mentor-protégé relationship will help the firm further develop or expand its current capabilities in that secondary NAICS code. SBA will not approve a mentor-protégé relationship in a secondary NAICS code in which the firm has no prior experience.

(2) A protégé firm may generally have only one mentor at a time. SBA may approve a second mentor for a particular protégé firm where the second relationship will not compete or otherwise conflict with the first mentor-protégé relationship, and:

* * * * *

(d) * * *

(1) * * *

(iii) Once a protégé firm no longer qualifies as a small business for the size standard corresponding to the NAICS code under which SBA approved its mentor-protégé relationship, any joint venture between the protégé and its mentor will not continue to receive the exclusion from affiliation authorized by paragraph (a) of this section. However, a change in the protégé's size status does not generally affect contracts previously awarded to a joint venture between the protégé and its mentor.

(A) * * *

(B) For contracts with durations of more than five years (including options), where size re-certification is required under § 121.404(g)(3) of this chapter no more than 120 days prior to the end of the fifth year of the contract

and no more than 120 days prior to exercising any option thereafter, once the protégé no longer qualifies as small for the size standard corresponding to the NAICS code assigned to the contract, the joint venture will not be able re-certify itself to be a small business for that contract. The rules set forth in § 121.404(g)(3) of this chapter apply in such circumstances.

* * * * *

(6) A mentor that provides a subcontract to a protégé that has its principal office located in the Commonwealth of Puerto Rico may (i) receive positive consideration for the mentor's past performance evaluation, and (ii) apply costs incurred for providing training to such protege toward the subcontracting goals contained in the subcontracting plan of the mentor.

(e) * * *

(1) * * *

(i) Specifically identify the business development assistance to be provided and address how the assistance will help the protégé enhance its growth and/or foster or acquire needed capabilities;

* * * * *

(5) Unless rescinded in writing as a result of an SBA review, the mentor-protégé relationship will automatically renew without additional written notice of continuation or extension to the protégé firm. * * *

(6) A protégé may generally have a total of two mentor-protégé agreements with different mentors.

(i) Each mentor-protégé agreement may be for an initial period of three years and may be extended an additional three years provided the protégé has received the agreed-upon business development assistance and will continue to receive additional assistance through the extended mentor-protégé agreement.

(ii) If a mentor-protégé agreement is terminated within a year from the date SBA approved the agreement, that mentor-protégé relationship will not count as one of the two mentor-protégé relationships that a small business may enter as a protégé.

* * * * *

(f) *Decision to decline mentor-protégé relationship.* Where SBA declines to approve a specific mentor-protégé agreement, SBA will issue a written decision setting forth its reason(s) for the decline. The small business concern seeking to be a protégé cannot attempt to enter into another mentor-protégé relationship with the same mentor for a period of 60 calendar days from the date of the final decision. The small business concern may, however, submit another proposed mentor-protégé agreement with a different proposed mentor at any time after the SBA's final decline decision.

(g) *Evaluating the mentor-protégé relationship.* SBA will review the mentor-protégé relationship annually. SBA will ask the protégé for its assessment of how the mentor-protégé relationship is working, whether or not the protégé received the agreed upon business development assistance, and whether the protégé would recommend the mentor to be a mentor for another small business in the future.

* * * * *

(4) SBA may decide not to approve continuation of a mentor-protégé agreement where:

(i) SBA finds that the mentor has not provided the assistance set forth in the mentor-protégé agreement;

(ii) SBA finds that the assistance provided by the mentor has not resulted in any material benefits or developmental gains to the protégé; or

(iii) A protégé does not provide information relating to the mentor-protégé relationship, as set forth in paragraph (g).

* * * * *

■ 43. Amend § 125.18 by:

■ a. Revising paragraph (a);

■ b. Removing ''(*see* §§ 125.9 and 124.520 of this chapter)'' and adding in its place ''(*see* § 125.9 of this chapter)'' in paragraph (b)(1)(ii);

■ c. Removing ''§ 124.520 or'' in paragraph (b)(2) introductory text;

■ d. Removing ''or § 124.520'' in paragraph (b)(3)(i);

■ e. Redesignating paragraphs (d)(1) through (4) as paragraphs (d)(2) through (5), respectively; and

■ f. Adding a new paragraph (d)(1).

The revision and addition read as follows:

§ 125.18 What requirements must an SDVO SBC meet to submit an offer on a contract?

(a) *General.* In order for a business concern to submit an offer and be eligible for the award of a specific SDVO contract, the concern must submit the appropriate representations and certifications at the time it submits its initial offer which includes price (or other formal response to a solicitation) to the contracting officer, including, but not limited to, the fact that:

(1) It is small under the size standard corresponding to the NAICS code(s) assigned to the contract;

(2) It is an SDVO SBC; and

(3) There has been no material change in any of its circumstances affecting its SDVO SBC eligibility.

* * * * *

(d) *Multiple Award Contracts*—(1) *SDVO status.* With respect to Multiple Award Contracts, orders issued against a Multiple Award Contract, and Blanket Purchase Agreements issued against a Multiple Award Contract:

(i) SBA determines SDVO small business eligibility for the underlying Multiple Award Contract as of the date a business concern certifies its status as an SDVO small business concern as part of its initial offer (or other formal response to a solicitation), which includes price, unless the firm was required to recertify under paragraph (e) of this section.

(A) Unrestricted Multiple Award Contracts or Set-Aside Multiple Award Contracts for Other than SDVO. For an unrestricted Multiple Award Contract or other Multiple Award Contract not specifically set aside for SDVO, if a business concern is an SDVO small business concern at the time of offer and contract-level recertification for the Multiple Award Contract, it is an SDVO small business concern for goaling purposes for each order issued against the contract, unless a contracting officer requests recertification as an SDVO small business for a specific order or Blanket Purchase Agreement. However, except for orders and Blanket Purchase Agreements issued off any Federal Supply Schedule contract, if an order or a Blanket Purchase Agreement under an unrestricted Multiple Award Contract is set-aside exclusively for SDVO small business, a concern must recertify that it qualifies as an SDVO small business at the time it submits its initial offer, which includes price, for the particular order or Blanket Purchase Agreement.

(B) SDVO Set-Aside Multiple Award Contracts. For a Multiple Award Contract that is specifically set aside for SDVO small business, if a business concern is an SDVO small business at the time of offer and contract-level recertification for the Multiple Award Contract, it is an SDVO small business for each order issued against the contract, unless a contracting officer requests recertification as an SDVO small business for a specific order or Blanket Purchase Agreement.

(ii) SBA will determine SDVO small business status at the time of initial offer (or other formal response to a solicitation), which includes price, for an order or an Agreement issued against a Multiple Award Contract if the contracting officer requests a new SDVO

small business certification for the order or Agreement.

* * * * *

■ 44. Amend § 125.28 by revising the section heading and adding a sentence to the end of paragraph (d)(1) to read as follows:

§ 125.28 What are the requirements for filing a service-disabled veteran-owned status protest?

* * * * *

(d) * * *

(1) * * * Except for an order or Blanket Purchase Agreement issued under any Federal Supply Schedule contract, an order or a Blanket Purchase Agreement that is set-aside or reserved for SDVO small business off a Multiple Award Contract that is not itself set aside for SDVO small business (or any SDVO order where the contracting officer has requested recertification of SDVO status), an interested party must submit its protest challenging the SDVO status of a concern for the order or Agreement by close of business on the fifth business day after notification by the contracting officer of the apparent successful offeror.

* * * * *

PART 126—HUBZONE PROGRAM

■ 45. The authority citation for part 126 continues to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), 644 and 657a.

§ 126.616 [Amended]

■ 46. Amend § 126.616 by removing ''(or, if also an 8(a) BD Participant, with an approved mentor authorized by § 124.520 of this chapter)'' in paragraph (a).

§ 126.618 [Amended]

■ 47. Amend § 126.618 by removing ''(or, if also an 8(a) BD Participant, under § 124.520 of this chapter)'' in paragraph (a).

■ 48. Amend § 126.801 by adding a sentence to the end of paragraph (d)(1) to read as follows:

§ 126.801 How does an interested party file a HUBZone status protest?

* * * * *

(d) * * *

(1) * * * In connection with an order or an Agreement that is set-aside or reserved for a certified HUBZone small business concern off a Multiple Award Contract that is not itself set aside for certified HUBZone small business concerns, except for an order or Blanket Purchase Agreement issued under any Federal Supply Schedule contact, (or any HUBZone set-aside order where the contracting officer has requested recertification of such status), an interested party must submit its protest challenging the HUBZone status of a concern for the order or Agreement by close of business on the fifth business day after notification by the contracting officer of the intended awardee of the order or Agreement.

* * * * *

PART 127—WOMEN-OWNED SMALL BUSINESS FEDERAL CONTRACT PROGRAM

■ 49. The authority citation for part 127 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 637(m), 644 and 657r.

§ 127.503 [Amended]

■ 50. Amend § 127.503 by removing paragraph (h).

■ 51. Revise § 127.504 to read as follows:

§ 127.504 What requirements must an EDWOSB or WOSB meet to be eligible for an EDWOSB or WOSB contract?

(a) *General.* In order for a business concern to submit an offer and be eligible for the award of a specific EDWOSB or WOSB contract, the concern must submit the appropriate representations and certifications at the time it submits its initial offer which includes price (or other formal response to a solicitation) to the contracting officer, including, but not limited to, the fact that:

(1) It is small under the size standard corresponding to the NAICS code(s) assigned to the contract;

(2) It is listed in SAM (or any successor system) as a WOSB or EDWOSB; and

(3) There has been no material change in any of its circumstances affecting its EDWOSB or WOSB eligibility.

(b) *Joint ventures.* A business concern seeking an EDWOSB or WOSB contract as a joint venture may submit an offer if the joint venture meets the requirements as set forth in § 127.506.

(c) *Multiple Award Contracts.* With respect to Multiple Award Contracts, orders issued against a Multiple Award Contract, and Blanket Purchase Agreements issued against a Multiple Award Contract:

(1) SBA determines EDWOSB or WOSB eligibility for the underlying Multiple Award Contract as of the date a concern certifies its status as an EDWOSB or WOSB as part of its initial offer (or other formal response to a solicitation), which includes price, unless the concern was required to recertify its status as a WOSB or EDWOSB under paragraph (f) of this section.

(i) Unrestricted Multiple Award Contracts or Set-Aside Multiple Award Contracts for Other than EDWOSB or WOSB. For an unrestricted Multiple Award Contract or other Multiple Award Contract not set aside specifically for EDWOSB or WOSB, if a business concern is an EDWOSB or WOSB at the time of offer and contract-level recertification for the Multiple Award Contract, it is an EDWOSB or WOSB for goaling purposes for each order issued against the contract, unless a contracting officer requests recertification as an EDWOSB or WOSB fora specific order or Blanket Purchase Agreement. However, except for orders and Blanket Purchase Agreements issued under any Federal Supply Schedule contract, if an order or a Blanket Purchase Agreement under an unrestricted Multiple Award Contract is set-aside exclusively for EDWOSB or WOSB, a concern must recertify it qualifies as an EDWOSB or WOSB at the time it submits its initial offer, which includes price, for the particular order or Agreement.

(ii) EDWOSB or WOSB Set-Aside Multiple Award Contracts. For a Multiple Award Contract that is set aside specifically for EDWOSB or WOSB, if a business concern is an EDWOSB or WOSB at the time of offer and contract-level recertification for the Multiple Award Contract, it is an EDWOSB or WOSB for each order issued against the contract, unless a contracting officer requests recertification as an EDWOSB or WOSB fora specific order or Blanket Purchase Agreement.

(2) SBA will determine EDWOSB or WOSB status at the time of initial offer (or other formal response to a solicitation), which includes price, for an order or an Agreement issued against a Multiple Award Contract if the contracting officer requests a new EDWOSB or WOSB certification for the order or Agreement.

(d) *Limitations on subcontracting.* A business concern seeking an EDWOSB or WOSB contract must also meet the applicable limitations on subcontracting requirements as set forth in § 125.6 of this chapter for the performance of contracts totally set aside for EDWOSB or WOSB, the performance of the set-aside portion of a partial set-aside contract, or the performance of orders set-aside for EDWOSB or WOSB. However, EDWOSB or WOSB concerns will not have to comply with the limitations on subcontracting provisions for any order issued against an unrestricted Multiple Award Contract if the order is competed amongst EDWOSB or WOSB concerns and at

least one other-than-small business concern.

(e) *Non-manufacturers.* An EDWOSB or WOSB that is a non-manufacturer, as defined in § 121.406(b) of this chapter, may submit an offer on an EDWOSB or WOSB contract for supplies, if it meets the requirements under the non-manufacturer rule set forth in § 121.406(b) of this chapter.

(f) *Recertification.* (1) Where a contract being performed by an EDWOSB or WOSB is novated to another business concern, the concern that will continue performance on the contract must recertify its status as an EDWOSB or WOSB to the procuring agency, or inform the procuring agency that it does not qualify as an EDWOSB or WOSB, within 30 days of the novation approval. If the concern cannot recertify its status as an EDWOSB or WOSB, the agency must modify the contract to reflect the new status, and may not count the options or orders issued pursuant to the contract, from that point forward, towards its women-owned small business goals.

(2) Where an EDWOSB or WOSB concern that is performing a contract acquires, is acquired by, or merges with another concern and contract novation is not required, the concern must, within 30 days of the transaction becoming final, recertify its EDWOSB or WOSB status to the procuring agency, or inform the procuring agency that it no longer qualifies as an EDWOSB or WOSB. If the concern is unable to recertify its status as an EDWOSB or WOSB, the agency must modify the contract to reflect the new status, and may not count the options or orders issued pursuant to the contract, from that point forward, towards its women-owned small business goals.

(3) For purposes of contracts (including Multiple Award Contracts) with durations of more than five years (including options), a contracting officer must request that a business concern recertify its EDWOSB or WOSB status no more than 120 days prior to the end of the fifth year of the contract, and no more than 120 days prior to exercising any option. If the concern is unable to recertify its status as an EDWOSB or WOSB, the agency must modify the contract to reflect the new status, and may not count the options or orders issued pursuant to the contract, from that point forward, towards its women-owned small business goals.

(4) A business concern that did not certify as an EDWOSB or WOSB, either initially or prior to an option being exercised, may recertify as an EDWOSB or WOSB for a subsequent option period if it meets the eligibility requirements at that time. The agency must modify the contract to reflect the new status, and may count the options or orders issued pursuant to the contract, from that point forward, towards its women-owned small business goals.

(5) Recertification does not change the terms and conditions of the contract. The limitations on subcontracting, nonmanufacturer and subcontracting plan requirements in effect at the time of contract award remain in effect throughout the life of the contract.

(6) A concern's status will be determined at the time of a response to a solicitation for an Agreement and each order issued pursuant to the Agreement.

§ 127.505 [Removed and Reserved]

■ 52. Remove and reserve § 127.505.

■ 53. Amend § 127.603 by revising the section heading and adding a sentence to the end of paragraph (c)(1) to read as follows:

§ 127.603 What are the requirements for filing an EDWOSB or WOSB status protest?

* * * * *

(c) * * *

(1) * * * Except for an order or Blanket Purchase Agreement issued under any Federal Supply Schedule contact, an order or a Blanket Purchase Agreement that is set-aside or reserved for EDWOSB or WOSB small business under a Multiple Award Contract that is not itself set aside for EDWOSB or WOSB small business (or any EDWOSB or WOSB order where the contracting officer has requested recertification of such status), an interested party must submit its protest challenging the EDWOSB or WOSB status of a concern for the order or Blanket Purchase Agreement by close of business on the fifth business day after notification by the contracting officer of the apparent successful offeror.

* * * * *

PART 134—RULES OF PROCEDURE GOVERNING CASES BEFORE THE OFFICE OF HEARINGS AND APPEALS

■ 54. The authority citation for part 134 continues to read as follows:

Authority: 5 U.S.C. 504; 15 U.S.C. 632, 634(b)(6), 634(i), 637(a), 648(l), 656(i), and 687(c); 38 U.S.C. 8127(f); E.O. 12549, 51 FR 6370, 3 CFR, 1986 Comp., p. 189.

Subpart J issued under 38 U.S.C. 8127(f)(8)(B).

Subpart K issued under 38 U.S.C. 8127(f)(8)(A).

■ 55. Amend § 134.318 by adding a subject heading to paragraph (a) and revising paragraph (b) to read as follows:

§ 134.318 NAICS Appeals.

(a) *General.* * * *

(b) *Effect of OHA's decision.* If OHA grants the appeal (changes the NAICS code), the contracting officer must amend the solicitation to reflect the new NAICS code. The decision will also apply to future solicitations for the same supplies or services.

* * * * *

Dated: October 16, 2019.

Christopher Pilkerton,

Acting Administrator.

[FR Doc. 2019–23141 Filed 11–7–19; 8:45 am]

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